SAFETY DATA SHEET

Letermovir Solid Formulation

Version 11.0  Revision Date: 04/04/2023  SDS Number: 58430-00024  Date of last issue: 10/01/2022  Date of first issue: 02/16/2015

SECTION 1. IDENTIFICATION

Product name: Letermovir Solid Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Liver, spleen, Blood)

GHS label elements
Hazard pictograms:

Signal Word: Warning

Hazard Statements:
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver, spleen, Blood) through prolonged or repeated exposure if swallowed.

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage: P405 Store locked up.

Disposal: P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

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></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Letermovir</td>
<td>917389-32-3</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
SAFETY DATA SHEET

Letemovir Solid Formulation

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
| Value type (Form of exposure): TWA (total dust) |
| Basis: OSHA Z-3 |

| 5 mg/m³ |
| Value type (Form of exposure): TWA (respirable fraction) |
| Basis: OSHA Z-3 |

| 15 Million particles per cubic foot |
| Value type (Form of exposure): TWA (respirable fraction) |
| Basis: OSHA Z-3 |

| Dust, nuisance dust and particulates | 10 mg/m³ |
| Value type (Form of exposure): PEL (Total dust) |
| Basis: CAL PEL |

| 5 mg/m³ |
| Value type (Form of exposure): PEL (respirable dust fraction) |
| Basis: CAL PEL |
### Engineering measures
Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment
#### Respiratory protection
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

#### Hand protection
Material: Chemical-resistant gloves

#### Eye protection
Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a...
potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Hygiene measures:
- Work uniform or laboratory coat.
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: Not applicable

Relative vapor density: Not applicable

Relative density: No data available

Density: No data available

Solubility(ies):
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- May form explosive dust-air mixture during processing, handling or other means.
- Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Acute dermal toxicity
LD50 (Rabbit): > 2,000 mg/kg

**Letermovir:**
Acute oral toxicity
LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 2,000 mg/kg

**Silicon dioxide:**
Acute oral toxicity
LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity
LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

**Magnesium stearate:**
Acute oral toxicity
LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

**Components:**

**Letermovir:**
Remarks: No data available

**Silicon dioxide:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Magnesium stearate:**
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials
Serious eye damage/eye irritation
Not classified based on available information.

Components:

Letermovir:
Remarks: No data available

Silicon dioxide:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Letermovir:
Remarks: No data available

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

**Letermovir:**

Genotoxicity in vitro
: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo
: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

Germ cell mutagenicity - Assessment
: Weight of evidence does not support classification as a germ cell mutagen.

**Silicon dioxide:**

Genotoxicity in vitro
: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative

Genotoxicity in vivo
: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative

**Magnesium stearate:**

Genotoxicity in vitro
: Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Remarks: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Cellulose:**

| Species | Rat |
**Application Route**: Ingestion  
**Exposure time**: 72 weeks  
**Result**: negative

**Silicon dioxide:**
| Species | Rat  
| Application Route | Ingestion  
| Exposure time | 103 weeks  
| Result | negative

**IARC**
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.

**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**
Suspected of damaging the unborn child.

**Components:**

**Cellulose:**
| Effects on fertility | Test Type: One-generation reproduction toxicity study  
| Species: Rat  
| Application Route: Ingestion  
| Result: negative

| Effects on fetal development | Test Type: Fertility/early embryonic development  
| Species: Rat  
| Application Route: Ingestion  
| Result: negative

**Letermovir:**
| Effects on fertility | Test Type: Fertility/early embryonic development  
| Species: Rat, female  
| Application Route: Oral  
| Fertility: NOAEL: 240 mg/kg body weight  
| Result: No effects on fertility.

Test Type: Fertility/early embryonic development  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 180 mg/kg body weight  
Result: No effects on fertility.  
Remarks: The significance of these findings for humans is not certain.

Test Type: Fertility/early embryonic development  
Species: Monkey, male  
Application Route: Oral
Fertility: NOAEL: 240 mg/kg body weight
Result: No effects on fertility.

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Developmental Toxicity: LOAEL: 250 mg/kg body weight
- Result: Embryo-fetal toxicity.
- Remarks: Maternal toxicity observed.

- Test Type: Embryo-fetal development
- Species: Rabbit
- Developmental Toxicity: LOAEL: 225 mg/kg body weight
- Result: Embryo-fetal toxicity.
  - Abortion
- Remarks: Maternal toxicity observed.

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on development, based on animal experiments.

Silicon dioxide:
Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

Magnesium stearate:
Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative
- Remarks: Based on data from similar materials

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Liver, spleen, Blood) through prolonged or repeated exposure if swallowed.

Components:

Letermovir:
- Routes of exposure: Ingestion
- Target Organs: Liver, spleen, Blood
- Assessment: May cause damage to organs through prolonged or repeated
### Repeated dose toxicity

#### Components:

**Cellulose:**
- Species: Rat
- NOAEL: $\geq 9,000$ mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

**Letermovir:**
- Species: Mouse
  - NOAEL: 40 mg/kg
  - LOAEL: 100 mg/kg
  - Application Route: Oral
  - Exposure time: 13 Weeks
  - Target Organs: Liver, spleen

- Species: Rat
  - NOAEL: 150 mg/kg
  - Application Route: Oral
  - Exposure time: 26 Weeks
  - Remarks: No significant adverse effects were reported

- Species: Monkey
  - NOAEL: 200 - 250 mg/kg
  - Application Route: Oral
  - Exposure time: 39 Weeks
  - Target Organs: Kidney

- Species: Rat
  - NOAEL: 60 mg/kg
  - LOAEL: 180 mg/kg
  - Exposure time: 13 Weeks
  - Target Organs: Testis, Blood, Liver, spleen, Immune system

- Species: Monkey
  - NOAEL: 30 mg/kg
  - LOAEL: 100 mg/kg
  - Application Route: Oral
  - Exposure time: 4 Weeks
  - Target Organs: Blood

**Silicon dioxide:**
- Species: Rat
- NOAEL: 1.3 mg/m³
- Application Route: inhalation (dust/mist/fume)
- Exposure time: 13 Weeks
Magnesium stearate:
| Species    | Rat               |
| NOAEL      | > 100 mg/kg       |
| Application Route | Ingestion         |
| Exposure time   | 90 Days           |
| Remarks      | Based on data from similar materials |

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Letermovir:**
| Ingestion | Symptoms: Diarrhea, Nausea, Vomiting, Headache, Dizziness, Fatigue, Back pain, Edema, Rash, muscle pain |

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cellulose:**
| Toxicity to fish | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l |
|                  | Exposure time: 48 h |
|                  | Remarks: Based on data from similar materials |

**Letermovir:**
| Toxicity to fish | LC50 (Menidia beryllina (Silverside)): > 100 mg/l |
|                  | Exposure time: 96 h |
|                  | Method: OECD Test Guideline 203 |

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Americamysis): 16 mg/l |
| Exposure time: 96 h |

| EC50 (Daphnia magna (Water flea)): > 100 mg/l |
| Exposure time: 48 h |
| Method: OECD Test Guideline 202 |

| Toxicity to algae/aquatic plants | EC50 (Pseudokirchneriella subcapitata (green algae)): > 8.8 mg/l |
| Exposure time: 72 h |
| Method: OECD Test Guideline 201 |
| Remarks: No toxicity at the limit of solubility. |

| NOEC (Pseudokirchneriella subcapitata (green algae)): 8.8 mg/l |
| Exposure time: 72 h |
| Method: OECD Test Guideline 201 |
| Remarks: No toxicity at the limit of solubility. |

| Toxicity to fish (Chronic tox- | NOEC (Pimephales promelas (fathead minnow)): 1 mg/l |
### Letermovir Solid Formulation

**Exposure time:**
- 32 d
- 21 d
- 3 h
- 96 h
- 72 h
- 48 h
- 47 h

**Method:**
- OECD Test Guideline 210
- OECD Test Guideline 211
- OECD Test Guideline 212
- OECD Test Guideline 209
- OECD Test Guideline 203
- OECD Test Guideline 201
- DIN 38412

**Remarks:**
- No toxicity at the limit of solubility.
- Based on data from similar materials.

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Exposure time:**
- 32 d
- 21 d
- 24 h
- 24 h
- 47 h
- 48 h
- 47 h
- 47 h

**Method:**
- OECD Test Guideline 211
- OECD Test Guideline 209
- OECD Test Guideline 202
- OECD Test Guideline 201

### Toxicity to microorganisms

**Exposure time:**
- 3 h
- 3 h
- 72 h

**Method:**
- OECD Test Guideline 209
- OECD Test Guideline 209

### Silicon dioxide:

**Toxicity to fish**

**Exposure time:**
- 96 h

**Method:**
- OECD Test Guideline 203

**Remarks:**
- Based on data from similar materials.

**Toxicity to daphnia and other aquatic invertebrates**

**Exposure time:**
- 24 h

**Method:**
- OECD Test Guideline 202

**Remarks:**
- Based on data from similar materials.

**Toxicity to algae/aquatic plants**

**Exposure time:**
- 72 h

**Method:**
- OECD Test Guideline 201

**Remarks:**
- Based on data from similar materials.

### Magnesium stearate:

**Toxicity to fish**

**Exposure time:**
- 48 h

**Method:**
- DIN 38412

**Remarks:**
- Based on data from similar materials.

**Toxicity to daphnia and other aquatic invertebrates**

**Exposure time:**
- 47 h

**Method:**

**Remarks:**
- Based on data from similar materials.
- No toxicity at the limit of solubility.

**Toxicity to algae/aquatic plants**

**Exposure time:**
- 1 mg/l

**Remarks:**
- Based on data from similar materials.
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

### Persistence and degradability

**Components:**

**Cellulose:**
- Biodegradability: Result: Readily biodegradable.

**Letermovir:**
- Biodegradability: Result: rapidly degradable
  - Biodegradation: 50 %
  - Exposure time: 6.7 d

**Magnesium stearate:**
- Biodegradability: Result: Not biodegradable
  - Remarks: Based on data from similar materials

### Bioaccumulative potential

**Components:**

**Letermovir:**
- Partition coefficient: n-octanol/water: log Pow: 2.29

**Magnesium stearate:**
- Partition coefficient: n-octanol/water: log Pow: > 4

### Mobility in soil

**Components:**

**Letermovir:**
- Distribution among environmental compartments: log Koc: 3.46
SAFETY DATA SHEET

Letemovir Solid Formulation

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations
- UNRTDG: Not regulated as a dangerous good
- IATA-DGR: Not regulated as a dangerous good
- IMDG-Code: Not regulated as a dangerous good
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable for product as supplied.

Domestic regulation
- 49 CFR: Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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:
- Combustible dust
- 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.
Safety Data Sheet

Letemovir Solid Formulation

Version 11.0  Revision Date: 04/04/2023  SDS Number: 58430-00024  Date of last issue: 10/01/2022  Date of first issue: 02/16/2015

US State Regulations

Pennsylvania Right To Know

- Cellulose 9004-34-6
- Letemovir 917389-32-3
- Croskarmellose sodium 74811-65-7
- Polyvinyl pyrrolidone 9003-39-8
- Silicon dioxide 7631-86-9

California List of Hazardous Substances

- Polyvinyl pyrrolidone 9003-39-8
- Silicon dioxide 7631-86-9

California Permissible Exposure Limits for Chemical Contaminants

- Cellulose 9004-34-6
- Silicon dioxide 7631-86-9
- Magnesium stearate 557-04-0

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

- Flammability: 1
- Health: 0
- Instability: 0
- Special hazard

HMIS® IV:

- HEALTH: *
- FLAMMABILITY: 3
- 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.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
SAFETY DATA SHEET
Letermovir Solid Formulation

Version: 11.0
Revision Date: 04/04/2023
SDS Number: 58430-00024
Date of last issue: 10/01/2022
Date of first issue: 02/16/2015

NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AOIC - 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 Chemicals and 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; TECI - Thailand Existing Chemicals 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


Revision Date: 04/04/2023

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.