1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Letermovir Solid Formulation

Manufacturer or supplier's details
Company : MSD
Address : 50 Tuas West Drive
           Singapore - Singapore 638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
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 : 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/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/
**SAFETY DATA SHEET**

**Letermovir Solid Formulation**

**Version** 4.0  
**Revision Date:** 10.10.2020  
**SDS Number:** 58429-00019  
**Date of last issue:** 23.03.2020  
**Date of first issue:** 16.02.2015

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**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

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**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

---

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance / Mixture :** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Letermovir</td>
<td>917389-32-3</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

---

**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**

Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

**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).

**Notes to physician**

Treat symptomatically and supportively.
5. FIREFIGHTING 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
Nitrogen oxides (NOx)
Metal oxides

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

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.

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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>Cellulose</td>
<td>9004-34-6</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Letermovir</td>
<td>917389-32-3</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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: If adequate local exhaust ventilation is not available or exp-
Filter type:  Particulates type
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:  powder
Colour:  No data available
Odour:  No data available
Odour 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
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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.

### 11. TOXICOLOGICAL INFORMATION

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

- **Acute toxicity**
  Not classified based on available information.

**Components:**

- **Cellulose:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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

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

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

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

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

**Letermovir:**
- Remarks: No data available

**Magnesium stearate:**
- Test Type: Maximisation Test
- Exposure routes: 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.
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

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 foetal 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 foetal development

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

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

Reproductive toxicity - Assessment

: Some evidence of adverse effects on development, based on animal experiments.

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 foetal development

: Test Type: Embryo-foetal 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:

Exposure routes: Ingestion
Target Organs: Liver, spleen, Blood
Assessment: May cause damage to organs through prolonged or repeated
Repeated dose toxicity

Components:

**Cellulose:**
- Species: Rat
- NOAEL: >= 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: 100 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

**Magnesium stearate:**
- Species: Rat
- NOAEL: > 100 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days
- Remarks: Based on data from similar materials
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Cellulose:**
- **Toxicity to fish:** \( LC_50 \) (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**Letermovir:**
- **Toxicity to fish:** \( LC_50 \) (Menidia beryllina (Silverside)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to daphnia and other aquatic invertebrates:** \( EC_50 \) (Americamysis): 16 mg/l
  - Exposure time: 96 h
- **Toxicity to algae/aquatic plants:** \( EC_50 \) (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 toxicity):** \( NOEC \) (Pimephales promelas (fathead minnow)): 1 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210
  - Remarks: No toxicity at the limit of solubility
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** \( NOEC \) (Daphnia magna (Water flea)): 1.2 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
**Toxicity to microorganisms**

EC50: > 972 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 29.6 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Magnesium stearate:**

**Toxicity to fish**

LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**

EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

**Toxicity to algae/aquatic plants**

EL50 (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  
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: \( n\text{-octanol/water} \) : log Pow: 2.29

**Magnesium stearate:**
- Partition coefficient: \( n\text{-octanol/water} \) : log Pow: > 4

**Mobility in soil**

**Components:**

**Letermovir:**
- Distribution among environmental compartments : log Koc: 3.46

**Other adverse effects**
No data available

**13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

- Waste from residues : Dispose of in accordance with local regulations.
- 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.

**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.
15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

- Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
- Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

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

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:


Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: dd.mm.yyyy

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- SG OEL: Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
- ACGIH / TWA: 8-hour, time-weighted average
- SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term
- AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; IARC - International Agency for Research on Cancer; IATA