SAFETY DATA SHEET

Letermovir Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Letermovir Solid Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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 Hazardous Products Regulations
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 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.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Letermovir</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range 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.
Rinse mouth thoroughly with water.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.

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.

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 fire fighting : 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 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>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>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC 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 (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC 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)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- 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: Work uniform or laboratory coat.

Hygiene measures: 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)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

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
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

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
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 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
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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 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., 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 fetal development: Test Type: Embryo-fetal development  
Species: Rat
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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 exposure.

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
LOAEL: 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

**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.

<table>
<thead>
<tr>
<th>Toxicty to fish (Chronic toxicity)</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 1.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 972 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>NOEC: 29.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: DIN 38412</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 47 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
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

Other adverse effects
No data available

SECTION 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.
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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS  :  not determined

DSL   :  not determined

IECSC :  not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH  :  USA. ACGIH Threshold Limit Values (TLV)


CA BC OEL :  Canada. British Columbia OEL

CA QC OEL :  Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

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

CA AB OEL / TWA :  8-hour Occupational exposure limit

CA BC OEL / TWA :  8-hour time weighted average

CA QC OEL / TWAEV :  Time-weighted average exposure value

AIClC - 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;
SAFETY DATA SHEET

Letermovir Solid Formulation

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 - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System


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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.

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