1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Letermovir Liquid Formulation

Manufacturer or supplier's details
Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
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
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

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>Letermovir</td>
<td>917389-32-3</td>
<td>&lt; 3</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:
Flush eyes with water as a precaution.
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:
None known.

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 fire-fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon 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.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for:
Soak up with inert absorbent material.
containment and cleaning up: For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe mist or vapours.
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.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers.
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>Letermovir</td>
<td>917389-32-3</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Colour: clear
Odour: odourless
Odour Threshold: No data available
pH: 7.5
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
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:

Letermovir:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
                      LD50 (Mouse): > 2,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

**Components:**

**Letermovir:**
Remarks : No data available

Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

**Letermovir:**
Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

**Components:**

**Letermovir:**
Remarks : No data available

Respiratory sensitisation
Not classified based on available information.

**Components:**

**Letermovir:**
Remarks : No data available

Germ cell mutagenicity
Not classified based on available information.

**Components:**

**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.

Carcinogenicity
Not classified based on available information.
Reproductive toxicity
Not classified based on available information.

**Components:**

**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.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Components:**

**Letermovir:**

**Exposure routes**
- Ingestion

**Target Organs**
- Liver, spleen, Blood

**Assessment**
- May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Letermovir:
Ingestion: Symptoms: Diarrhoea, Nausea, Vomiting, Headache, Dizziness, Fatigue, Back pain, Oedema, Rash, muscle pain
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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 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

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

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

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
Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : 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


Date format : yyyy/mm/dd

Full text of other abbreviations

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 - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-
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