

## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Letermovir Solid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, spleen, Blood)

Short-term (acute) aquatic hazard : Category 3

##### 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.  
H402 Harmful to aquatic life.

## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

Precautionary statements :

**Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe dust.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P318 IF exposed or concerned, get medical advice.

**Storage:**  
P405 Store locked up.

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

### 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

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 - < 50
Letermovir	917389-32-3	>= 30 - < 50
Silicon dioxide	7631-86-9	>= 1 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5

## 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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).
Notes to physician	: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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 Metal oxides Nitrogen oxides (NO <sub>x</sub> )
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	: Sweep up or vacuum up spillage and collect in suitable con-

## Letermovir Solid Formulation

Version 5.1      Revision Date: 14.04.2025      SDS Number: 59341-00025      Date of last issue: 30.09.2023  
Date of first issue: 16.02.2015

containment and cleaning up      tainer 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Letermovir	917389-32-3	TWA	0.4 mg/m <sup>3</sup> (OEB 2)	Internal
Silicon dioxide	7631-86-9	TWA (Total dust)	10 mg/m <sup>3</sup> (Silica)	IN OEL
Magnesium stearate	557-04-0	TWA (Inhal-)	10 mg/m <sup>3</sup>	ACGIH

## Letermovir Solid Formulation

Version 5.1      Revision Date: 14.04.2025      SDS Number: 59341-00025      Date of last issue: 30.09.2023  
Date of first issue: 16.02.2015

		able particulate matter)		
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

**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** : Chemical-resistant gloves

**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** : 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

## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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 characteristics Particle size	:	No data available

### 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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.

#### 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

##### 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

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

##### Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

---

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

##### **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  
Method : OECD Test Guideline 405  
Result : No eye irritation

##### **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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

### 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.

#### **Silicon dioxide:**

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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

### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

### 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.

### Silicon dioxide:

- Effects on foetal development : Test Type: Embryo-foetal 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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 exposure.

### 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 : 100 mg/kg  
LOAEL : 200 - 250 mg/kg  
Application Route : Oral  
Exposure time : 39 Weeks  
Target Organs : Kidney

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

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/m<sup>3</sup>  
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: Diarrhoea, Nausea, Vomiting, Headache, Dizziness, Fatigue, Back pain, Oedema, Rash, muscle pain

## 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

- 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 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
- Toxicity to fish (Chronic toxicity) : NOEC: 1 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Silicon dioxide:

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 24 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 ( Desmodesmus subspicatus (green algae)): > 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

Remarks: Based on data from similar materials

NOEC ( Desmodesmus subspicatus (green algae)): 10,000 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

### 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  
Method: Directive 67/548/EEC, Annex V, C.2.  
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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

---

### 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

---

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues	: Do not dispose of waste into sewer. 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 IMO instruments

Not applicable for product as supplied.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

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

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

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

## 16. OTHER INFORMATION

Revision Date : 14.04.2025

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
IN OEL	:	India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA	:	8-hour, time-weighted average
IN OEL / TWA	:	Time-Weighted Average Concentration (TWA) (8 hrs.)

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 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.1	14.04.2025	59341-00025	Date of first issue: 16.02.2015

---

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

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.

IN / EN