

Letermovir Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 66864-00020 Date of first issue: 27.02.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Letermovir Liquid Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 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 mist or vapors.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:



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P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Letermovir	917389-32-3	>= 1 -< 5	

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. Flush eyes with water as a precaution.

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

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

delayed

exposure if swallowed.

Protection of first-aiders : First Aid responders show

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

nedia

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides



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Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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 containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. Do not breathe mist or vapors.

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working



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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.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Letermovir	917389-32-3	TWA	0.4 mg/m3 (OEB 2)	Internal

Engineering measures: Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less 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

Hand protection

Particulates type

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear



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Odor : odorless

Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

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 : No data available

Explosive properties : Not explosive

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

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY



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Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

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 toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

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 sensitization

Skin sensitization

Not classified based on available information.



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Respiratory sensitization

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

Suspected of damaging the unborn child.

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



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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 - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

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:

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



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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: Diarrhea, Nausea, Vomiting, Headache, Dizzi-

ness, Fatigue, Back pain, Edema, Rash, muscle pain

SECTION 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



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Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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 environ-

mental compartments

log Koc: 3.46

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.



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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

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

: Hydrochloric acid

producing capsules, tablets and pills.

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

AICS not determined

DSL not determined

IECSC not determined

SECTION 16. OTHER INFORMATION

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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



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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 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

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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8