

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Letermovir Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised againstUse of the Sub-
stance/Mixture : PharmaceuticalRecommended restrictions
on use : Not applicable**1.3 Details of the supplier of the safety data sheet**Company : MSD
117 16th Road
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com**1.4 Emergency telephone number**

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:
Letermovir

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Letermovir	917389-32-3	Repr. 2; H361d STOT RE 2; H373 (Liver, spleen, Blood)	>= 30 - < 50

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of 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.

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).

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

- | | | |
|-------------------------|---|---|
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | 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. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|
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SECTION 5: Firefighting measures**5.1 Extinguishing media**

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|---|
| 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 _x) |

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- 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.
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SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- 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.

Letermovir Solid Formulation

Version 5.2 Revision Date: 14.04.2025 SDS Number: 58431-00024 Date of last issue: 30.09.2023
Date of first issue: 16.02.2015

- 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.
- 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.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OEL-RL	10 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Letermovir	917389-32-3	TWA	0.4 mg/m ³ (OEB 2)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Silicon dioxide	Workers	Inhalation	Long-term systemic effects	4 mg/m ³

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

8.2 Exposure controls**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

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
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 (P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

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.

9.2 Other information

Particle size	:	No data available
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SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of : Inhalation

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

exposure	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
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Serious eye damage/eye irritation

Not classified based on available information.

Components:**Letermovir:**

Remarks	:	No data available
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Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Letermovir:**

Remarks	:	No data available
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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

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

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 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.

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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
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

Aspiration toxicity

Not classified based on available information.

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

Experience with human exposure

Components:

Letermovir:

Ingestion : Symptoms: Diarrhoea, Nausea, Vomiting, Headache, Dizziness, Fatigue, Back pain, Oedema, Rash, muscle pain

SECTION 12: Ecological information

12.1 Toxicity

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 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	:	NOEC: 1,2 mg/l

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability**Components:****Letermovir:**

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 6,7 d

12.3 Bioaccumulative potential**Components:****Letermovir:**

Partition coefficient: n-octanol/water : log Pow: 2,29

12.4 Mobility in soil**Components:****Letermovir:**

Distribution among environmental compartments : log Koc: 3,46

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

Contaminated packaging : discussion with the waste disposal authorities.
Do not dispose of waste into sewer.
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

14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

SECTION 15: Regulatory information**15.1 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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H361d	:	Suspected of damaging the unborn child.
H373	:	May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 - Interna-

Letermovir Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	14.04.2025	58431-00024	Date of first issue: 16.02.2015

tional Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Repr. 2	H361d
STOT RE 2	H373

Classification procedure:

Calculation method
Calculation method

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.

ZA / EN