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1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Letermovir Liquid Formulation
Supplier's company name, ac Company name of supplier		ess and phone number MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Letermovir	917389-32-3	>= 1 - < 2.5	

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately.
		When symptoms persist or in all cases of doubt seek medical



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	lf inhale In case	ed of skin contact	:	of water. Remove contamir Get medical atten	tion. , immediately flush skin with soap and plenty nated clothing and shoes. tion.
	lf swalld		:	Flush eyes with w Get medical atten If swallowed, DO Get medical atten Rinse mouth thore	shoes before reuse. ater as a precaution. tion if irritation develops and persists. NOT induce vomiting. tion.
	and effe delayed Protecti	nportant symptoms ects, both acute and d ion of first-aiders o physician	:	and use the recon when the potentia	ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8). cally and supportively.
5. FI		ITING MEASURES			, , , ,
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
	Specific fighting	c hazards during fire-	:	Exposure to comb	oustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firefi	protective equipment ighters	:		e, wear self-contained breathing apparatus. ective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-



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• •	/ procedures			t recommendations (see section 8).
Enviro	onmental precautions	:	Prevent spreadin barriers). Retain and dispo	eakage or spillage if safe to do so. g over a wide area (e.g. by containment or c se of contaminated wash water. should be advised if significant spillages
	ods and materials for inment and cleaning up	:	For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	rt absorbent material. provide dyking or other appropriate contain- terial from spreading. If dyked material can a recovered material in appropriate container ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational requirements.

Handling

nananng	
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 as-
	sessment
	Take care to prevent spills, waste and minimize release to the
	environment.
Avoidance of contact	: Oxidizing agents
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.



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Stora	age		
Cond	litions for safe storage		rly labelled containers.
Mate	rials to avoid		dance with the particular national regulations. vith the following product types: ng agents
Pack	aging material	: Unsuitable ma	aterial: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	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 equipme	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Hand protection Material	:	Chemical-resistant gloves
Eye protection Skin and body 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. Work uniform or laboratory coat.
Skin and body protection	•	

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	clear
Odour	:	odourless





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	Odour	Threshold	:	No data available)
	Melting	point/freezing point	:	No data available	9
		point, initial boiling nd boiling range	:	No data available	3
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	:	No data available	9
	Upp	explosion limit and upp per explosion limit / Up- flammability limit			
		ver explosion limit / ver flammability limit	:	No data available)
	Flash p	point	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	7.5	
	Evapor	ration rate	:	No data available	9
	Auto-ig	nition temperature	:	No data available	
	Viscosi Visc	ity cosity, kinematic	:	No data available	9
	Solubil Wat	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Vapour	rpressure	:	No data available	9
		/ and / or relative densi ative density	ty :	No data available)
	Der	nsity	:	No data available	9
	Relativ	e vapour density	:	No data available	9
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	r mixture is not classified as oxidizing.





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	cle characteristics article size	: No	ot applicable	
10. STAB	ILITY AND REACTIVIT	ŕ		
	tivity nical stability ibility of hazardous reac-	: St	able under nor	a reactivity hazard. mal conditions. rong oxidizing agents.
Incon Haza	ons conditions to avoid : None known. ncompatible materials : Oxidizing agents lazardous decomposition : No hazardous decomposition products are known. roducts			
11. TOXIC	COLOGICAL INFORMA	TION		
Inforr expo	nation on likely routes of sure	Ski Ing	alation n contact estion e contact	
Not c	e toxicity lassified based on availa ponents:	able info	mation.	
	movir:			
Acute	e oral toxicity	: LD:	50 (Rat): > 2,0	00 mg/kg
		LD	50 (Mouse): >	2,000 mg/kg
-	corrosion/irritation lassified based on availa	able info	mation.	
<u>Com</u>	ponents:			
Leter Rema	movir: arks	: No	data available	
	ous eye damage/eye irr lassified based on availa		mation.	
Com	ponents:			
Leter Rema	movir: arks	: No	data available	





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Resp	iratory or skin sensit	tisatio	n	
-	sensitisation lassified based on ava	ilable	information.	
-	iratory sensitisation lassified based on ava	ilable	information.	
Com	ponents:			
Leter Rema	r movir: arks	:	No data availab	le
Not c	n cell mutagenicity lassified based on ava ponents:	ilable	information.	
Leter	movir:			
	ptoxicity in vitro	:	Test Type: Bact Result: negative	terial reverse mutation assay (AMES)
			Test Type: Chro Result: negative	omosome aberration test in vitro
Geno	otoxicity in vivo	:	cytogenetic ass Species: Mouse	e ite: Intraperitoneal injection
	n cell mutagenicity - ssment	:	Weight of evide cell mutagen.	nce does not support classification as a ger
	inogenicity lassified based on ava	ilable	information.	
Repr	oductive toxicity			
Not c	lassified based on ava	ilable	information.	
Com	ponents:			
	rmovir: ts on fertility	:	Species: Rat, fe Application Rou	ite: Oral _: 240 mg/kg body weight
			Species: Rat, m Application Rou	



rsion)	Revision Date: 2024/09/28	SDS Number: 66862-00023	Date of last issue: 2024/04/06 Date of first issue: 2015/02/27
Effects	s on foetal develop-	Remarks: The certain. Test Type: Fe Species: Mon Application R Fertility: NOA Result: No eff Test Type: Er Species: Rat Development Remarks: Ma Test Type: Er Species: Rab Development Result: Embr Abortion	oute: Oral EL: 240 mg/kg body weight fects on fertility mbryo-foetal development al Toxicity: LOAEL: 250 mg/kg body weight yo-foetal toxicity ternal toxicity observed. mbryo-foetal development
	ductive toxicity - As- nent	: Some eviden animal experi	ce of adverse effects on development, based o

Components:

Letermovir:

Exposure routes	: Ingestion	
Target Organs	: Liver, sple	en, Blood
Assessment	: May cause	damage to organs through prolonged or repeated
	exposure.	

Repeated dose toxicity

Components:

Letermovir:

Species NOAEL	:	Mouse
NOAEL	:	40 mg/kg
LOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Liver, spleen



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	EL cation Route sure time	: Rat : 150 mg/kg : Oral : 26 Weeks : No significar	nt adverse effects were reported
Expos	EL	: Monkey : 100 mg/kg : 200 - 250 m : Oral : 39 Weeks : Kidney	g/kg
	EL	: Rat : 60 mg/kg : 180 mg/kg : 13 Weeks : Testis, Blood	d, Liver, spleen, Immune system
Expos	EL	: Monkey : 30 mg/kg : 100 mg/kg : Oral : 4 Weeks : Blood	
Not cl	ration toxicity lassified based on availa rience with human exp		
	oonents: movir: tion		Diarrhoea, Nausea, Vomiting, Headache, Dizzi- e, Back pain, Oedema, Rash, muscle pain
12. ECOL	OGICAL INFORMATIO	N	
Ecoto	oxicity		
Com	oonents:		
	movir: ity to fish	Exposure tin	lia beryllina (Silverside)): > 100 mg/l ne: 96 h CD Test Guideline 203
Toxic	ity to daphnia and other	: EC50 (Amer	icamysis): 16 mg/l





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			EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxicity plants	y to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
			mg/l Exposure time: 72 Method: OECD To	
Toxicity icity)	y to fish (Chronic tox-	:	Exposure time: 32 Method: OECD Te	
	y to daphnia and other invertebrates (Chron- ity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Toxicity	y to microorganisms	:	EC50: > 972 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
			NOEC: 29.6 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	ation inhibition
Persis	tence and degradabili	ity		
Compo	onents:			
Leterm Biodeg	novir: radability	:	Result: rapidly de Biodegradation: & Exposure time: 6.	50 %
Bioaco	umulative potential			
Compo	onents:			
Leterm Partitio octanol	n coefficient: n-	:	log Pow: 2.29	



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Mobi	lity in soil		
Com	ponents:		
Distri	r movir: bution among environ- al compartments	: log Koc: 3.46	
	rdous to the ozone lay	/er	
	r adverse effects ata available		
13. DISPO	OSAL CONSIDERATIO	NS	
Disn	osal methods		
-	e from residues		ccordance with local regulations. of waste into sewer.
Conta	aminated packaging	: Empty containe dling site for red	ers should be taken to an approved waste han- cycling or disposal. specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION	١	
Inter	national Regulations		
Prope Class Subs Pack Labe Envir	umber er shipping name s idiary risk ing group ls onmentally hazardous	 Not applicable no 	
IATA	-DGR		

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo	:	Not applicable
aircraft)		
Packing instruction (passen-	:	Not applicable
ger aircraft)		
IMDG-Code		
	_	Nist smallssiple
UN number	•	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk		Not applicable
	•	





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Packing group	: Not a	pplicable
Labels	: Not a	pplicable
EmS Code	: Not a	pplicable
Marine pollutant	: Not a	pplicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2) Not applicable





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tions	-	es (Article 577-2 of the	Occupational Health and Safety Regula-
	ance on Preventior	n of Hazards Due to S	pecified Chemical Substances
	ance on Preventior	n of Lead Poisoning	
	ance on Preventior	n of Tetraalkyl Lead P	oisoning
	ance on Preventior	n of Organic Solvent I	Poisoning
Subs	cement Order of th tances) oplicable	e Industrial Safety an	d Health Law - Attached table 1 (Dangero
		ous Substances Contr	ol Law
	pplicable		
Act o	n Confirmation, etc		of Specific Chemical Substances in the the Management Thereof
Not a	pplicable		
-	Pressure Gas Safet	y Act	
-	osive Control Law		
	el Safety Law egulated as a danger	ous good	
	ion Law	Ũ	
	egulated as a danger	ous good	
Marin	e Pollution and Sea	a Disaster Prevention	etc Law
Bulk t	ransportation	: Not classified a	as noxious liquid substance
	transportation		as marine pollutant
Narco	otics and Psychotro		
Narco Not aj Speci	otic or Psychotropic R pplicable fic Narcotic or Psych	Raw Material (Export / I	mport Permission) Export / Import permission)
	pplicable		
	e Disposal and Pub trial waste	lic Cleansing Law	
The c	components of this	product are reported	in the following inventories:



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DSL		: not determined	
IECSC	:	: not determined	

16. OTHER INFORMATION

Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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 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

SAFETY DATA SHEET



Letermovir Liquid Formulation

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN