

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

SECTION 1. IDENTIFICATION

Product name : Molnupiravir Capsule Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
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@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Specific target organ toxicity : Category 1 (Gastrointestinal tract)
- repeated exposure (Oral)

Other hazards

|| Dust contact with the eyes can lead to mechanical irritation.

Hazards associated with a change in physical form:

Conditions	Hazards
If small particles are generated during further processing, handling or by other means.	May form combustible dust concentrations in air.

GHS label elements

|| Hazard pictograms : 

|| Signal Word : Danger

|| Hazard Statements : H372 Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

|| Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

P314 Get medical attention if you feel unwell.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Cellulose	9004-34-6*	>= 23.5 - <= 84.75	-
Molnupiravir	2492423-29-5*	>= 8.75 - <= 70	-

* Indicates that the identifier is a CAS No.

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 if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with 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 if symptoms occur.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure if swallowed.
Dust contact with the eyes can lead to mechanical irritation.
No information available.
- 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.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

- 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
- 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 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 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 containment and 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.
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SECTION 7. HANDLING AND STORAGE

- || Technical measures : Static electricity may accumulate and ignite suspended dust
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SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

Local/Total ventilation	:	causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Advice on safe handling	:	Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
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 Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m ³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m ³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m ³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m ³

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020



Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Molnupiravir	2492423-29-5	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100cm ²	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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. Additional body garments should be used based upon the

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

Hygiene measures : task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white to off-white
Odor	:	No data available
Odor 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)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

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 : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
Particle size : No data available

SECTION 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.

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cellulose:

|| Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

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

Molnupiravir:

Acute oral toxicity : LD0 (Rat): 2,000 mg/kg
LD0 (Dog): 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Molnupiravir:

Species : reconstructed human epidermis (RhE)
Method : EpiDerm
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Molnupiravir:

Species : Bovine cornea
Result : No eye irritation
Method : Bovine cornea (BCOP)

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

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)

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Molnupiravir:

Genotoxicity in vitro : Test Type: Ames test
Result: positive

Test Type: Micronucleus test
Test system: human lymphoblastoid cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Rat
Cell type: Bone marrow
Result: equivocal

Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Transgenic rat
Application Route: Oral
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.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

Reproductive toxicity

Not classified based on available information.

Components:

Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on fetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

Molnupiravir:

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: > 200 mg/kg body weight Symptoms: Effects on embryofetal and postnatal development. Result: No effects on fertility and early embryonic development were detected. Remarks: Not classified due to data which are conclusive although insufficient for classification.
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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Components:

Molnupiravir:

Routes of exposure	:	Oral
Target Organs	:	Gastrointestinal tract
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

|| Exposure time : 90 Days

Molnupiravir:

|| Species : Rat
|| LOAEL : 2,000 mg/kg
|| Exposure time : 7 d
|| Target Organs : Stomach

|| Species : Dog
|| LOAEL : 300 mg/kg
|| Exposure time : 7 d
|| Target Organs : Gastrointestinal tract
|| Symptoms : tachycardia, decreased activity, decrease in appetite, Diarrhea, Vomiting

|| Species : Rat
|| NOAEL : 500 mg/kg
|| Exposure time : 28 d

|| Species : Dog
|| NOAEL : 6 mg/kg
|| LOAEL : 17 mg/kg
|| Exposure time : 28 d
|| Target Organs : Gastrointestinal tract
|| Symptoms : decreased activity, Gastrointestinal tract damage, decrease in appetite

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Molnupiravir:

|| General Information : Symptoms: Headache, Gastrointestinal disturbance
Remarks: The most common side effects are:
Symptoms: Back pain

SECTION 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

Molnupiravir:

|| Toxicity to algae/aquatic : EC10 (Raphidocelis subcapitata (freshwater green alga)): 89

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

plants	:	mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	EC10 (Pimephales promelas (fathead minnow)): 5.8 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10 (Daphnia magna (Water flea)): > 8.8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility.
Toxicity to microorganisms	:	EC10: 143.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.

Persistence and degradability

Components:

Cellulose:

Biodegradability	:	Result: Readily biodegradable.
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Molnupiravir:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 81 % Exposure time: 28 d Method: OECD Test Guideline 314
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Bioaccumulative potential

Components:

Molnupiravir:

Partition coefficient: n-octanol/water	:	log Pow: -0.534 pH: 7
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Mobility in soil

Components:

Molnupiravir:

Distribution among environ-	:	OECD Test Guideline 106
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SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

|| mental compartments log Koc: 1.45

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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 IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

|| SARA 311/312 Hazards : Specific target organ toxicity (single or repeated exposure)

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version 10.1 Revision Date: 12/08/2025 SDS Number: 6199216-00016 Date of last issue: 06/20/2025
Date of first issue: 08/24/2020

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Cellulose	9004-34-6
Molnupiravir	2492423-29-5
Croscarmellose sodium	74811-65-7
Hydroxypropyl cellulose	9004-64-2

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
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The ingredients of this product are reported in the following inventories:

AICS : not determined

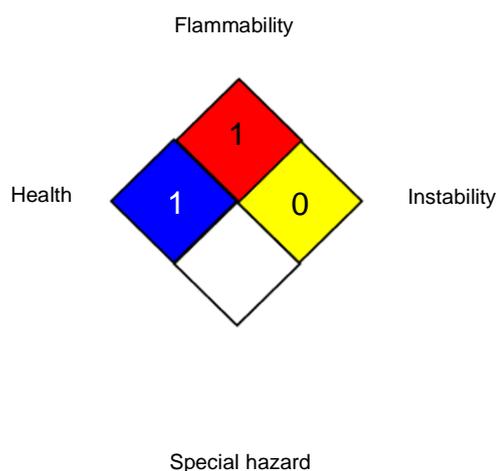
CA. DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organization 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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/
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Revision Date	:	12/08/2025
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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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/20/2025
10.1	12/08/2025	6199216-00016	Date of first issue: 08/24/2020

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.

US / Z8