# SAFETY DATA SHEET
according to the Globally Harmonized System

# Molnupiravir Capsule Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.07.2024 |
|---|---|---|---|
| 8.0 | 28.09.2024 | 6199210-00014 | Date of first issue: 24.08.2020 |

## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Molnupiravir Capsule Formulation

**Manufacturer or supplier's details**

Company : MSD

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

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

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

**Classification**

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

**GHS Classification**

Skin corrosion/irritation : Category 3

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

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H316 Causes mild skin irritation.
H372 Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P264 Wash hands thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

**Response:**

P319 Get medical help if you feel unwell.
P332 + P317 If skin irritation occurs: Get medical help.

**Disposal:**

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

**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Cellulose | 9004-34-6 | >= 70 - < 90 |
| Molnupiravir | 2492423-29-5 | >= 70 - < 90 |

## 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 mild skin irritation.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Metal oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

### 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Cellulose | 9004-34-6 | TWA | 10 mg/m3 | ACGIH |
| Molnupiravir | 2492423-29-5 | TWA | 20 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 200 µg/100cm2 | 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 | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Particulates type |

Hand protection

| | | |
|---|---|---|
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Eye protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | solid |
| Colour | : | white to off-white |
| 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) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |

| | | |
|---|---|---|
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | No data available |

## 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## 11. TOXICOLOGICAL INFORMATION

| | | |
|---|---|---|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**
Not classified based on available information.

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**Molnupiravir:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD0 (Rat): 2,000 mg/kg<br><br>LD0 (Dog): 2,000 mg/kg |

**Skin corrosion/irritation**
Causes mild skin irritation.

**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 |
| Method | : | Bovine cornea (BCOP) |
| Result | : | No eye irritation |

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
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)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Molnupiravir:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Ames test<br>Result: positive<br><br>Test Type: Micronucleus test<br>Test system: human lymphoblastoid cells<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative<br><br>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Cell type: Bone marrow<br>Result: equivocal<br><br>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Transgenic rat<br>Application Route: Oral<br>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 |

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Cellulose:**

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

**Molnupiravir:**

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

**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:**

| | | |
|---|---|---|
| Exposure routes | : | 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 |
| 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, Diarrhoea, 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<br>Remarks: The most common side effects are:<br>Symptoms: Back pain |

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |

**Molnupiravir:**

| | | |
|---|---|---|
| Toxicity to algae/aquatic plants | : | EC10 ( Raphidocelis subcapitata (freshwater green alga)): 89 mg/l<br>End point: Growth<br>Exposure time: 72 h |

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

**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. |

**Molnupiravir:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 81 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |

**Bioaccumulative potential**

**Components:**

**Molnupiravir:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -0.534<br>pH: 7 |

**Mobility in soil**

**Components:**

**Molnupiravir:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | OECD Test Guideline 106<br>log Koc: 1.45 |

**Other adverse effects**
No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to IMO instruments**
Not applicable for product as supplied.

**Special precautions for user**
Not applicable

## 15. REGULATORY INFORMATION

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

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## 16. OTHER INFORMATION

| | | |
|---|---|---|
| Revision Date | : | 28.09.2024 |

**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/ |

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

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

IN / EN