

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

Section 1: Identification

Product identifier : Molnupiravir Capsule Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Manufacturer or supplier's details


Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

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

GHS Label elements, including precautionary statements

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: P314 Get medical advice/ attention if you feel unwell. Disposal:

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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

Other hazards which do not result in classification

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

Section 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

Section 4: First-aid measures**Description of necessary 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

Risks : 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures**Extinguishing media**

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.0	20.06.2025	6199215-00016	14.04.2025
			Date of first issue: 24.08.2020

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

Unsuitable extinguishing media : None known.

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

Special protective actions for fire-fighters

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.

Section 6: Accidental release measures**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).

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.

Methods and materials 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.

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage**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. |
| Advice on safe handling | : | 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. |
| 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. |

Conditions for safe storage, including any incompatibilities

- | | | |
|-----------------------------|---|--|
| Conditions for safe storage | : | Keep in properly labelled containers.
Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:
Strong oxidizing agents |

Molnupiravir Capsule Formulation

Version 8.0 Revision Date: 20.06.2025 SDS Number: 6199215-00016 Date of last issue: 14.04.2025
 Date of first issue: 24.08.2020

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	PEL (long term)	10 mg/m ³	SG OEL
		TWA	10 mg/m ³	ACGIH
Molnupiravir	2492423-29-5	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100cm ²	Internal

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

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.

Skin protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

Section 9: Physical and chemical properties

Appearance : powder

Molnupiravir Capsule Formulation

Version 8.0	Revision Date: 20.06.2025	SDS Number: 6199215-00016	Date of last issue: 14.04.2025 Date of first issue: 24.08.2020
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II

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

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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

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.

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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 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) Result: negative
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	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
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Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative
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Molnupiravir:

Genotoxicity in vitro	:	Test Type: Ames test Result: positive
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	:	Test Type: Micronucleus test Test system: human lymphoblastoid cells Result: negative
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Genotoxicity in vivo	:	Test Type: Micronucleus test
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Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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

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 foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Molnupiravir:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

Developmental Toxicity: LOAEL: > 200 mg/kg body weight
Symptoms: Effects on embryofoetal 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.

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
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Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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**Toxicity****Components:****Cellulose:**

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

Molnupiravir:

Toxicity to algae/aquatic plants	:	EC10 (<i>Raphidocelis subcapitata</i> (freshwater green alga)): 89 mg/l
		End point: Growth
		Exposure time: 72 h
		Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	EC10 (<i>Pimephales promelas</i> (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 (<i>Daphnia magna</i> (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

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

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.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Bioaccumulative potential**Components:****Molnupiravir:**

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

Mobility in soil**Components:****Molnupiravir:**

Distribution among environ- : OECD Test Guideline 106
mental compartments log Koc: 1.45

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

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

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**

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

UNRTDG

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

IATA-DGR

UN/ID No.	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

IMDG-Code

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
EmS Code	: Not applicable
Marine pollutant	: Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information**Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	: Not applicable
Fire Safety (Petroleum and Flammable Materials) Regulations	: Not applicable

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

AICS	: not determined
DSL	: not determined

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

IECSC : not determined

Section 16: Other information

Revision Date : 20.06.2025

Further informationSources 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 abbreviationsACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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 - Trans-

Molnupiravir Capsule Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
8.0	20.06.2025	6199215-00016	Date of first issue: 24.08.2020

portation 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.

SG / EN