



Beijing Lepu Medical Technology Co., Ltd.

According to (EC) No. 1272/2008[EU-GHS/CLP]

Material Safety Data Sheet (MSDS)

Product Name:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)
Model No.:	/

Written by: Linda
(Linda)

Inspected by: Jose
(Jose)



ISSUED BY: TUV-Laboratory (China) Service of Testing Co., Ltd.

Sept. 2020 PRINT

Item No.:	20A010A027
MSDS No.:	EMS.200.907.018.LMT
Initial Date:	Sept. 07, 2020
Revision Date:	Sept. 07, 2020



Material Safety Data Sheet

Product Name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Version: 1.0

Initial Date: Sept. 07, 2020

Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Section 1

Product and Company Identification

Product identification

Product name:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)
Model No.:	/
CAS No.:	Not applicable
EC No.:	Not applicable
Molecular formula:	Not applicable

Relevant identified uses of the substance or mixture and uses advised against

Identified uses:	used for qualitative detection of new coronavirus (SARS-CoV-2) antigen in clinical samples (nasal swabs)
Uses advised against:	No special note

Details of the applicant, supplier

Company name:	Beijing Lepu Medical Technology Co., Ltd.
Address:	Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
Post code:	/
Telephone:	+86-15810326252
Fax:	/
E-mail:	/

Emergency telephone number

Emergency telephone:	+86-18333609628
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Section 2

Hazard Description

Hazard class and label elements of the product according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:

GHS Hazard class

	Non-hazardous substance or mixture.
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Item No.: 20A010A027

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GHS label elements

Pictogram(s):	None
Signal word:	None

Hazard statements

	Not applicable.
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Other Hazards

	None.
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Hazard description

Physical and chemical hazards

	Non-flammable, no special combustion and explosion characteristics.
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Health hazards

Inhalation:	None.
Ingestion:	Abdominal pain.
Skin contact:	None.
Eye contact:	Redness, pain, tears.

Environmental hazards

	None.
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Section 3

Composition/Ingredient Data

Material

Mixture

Component(s)	Content, %	CAS No.
Test strip shell (Hydrophobic hard card)	60.0	65996-61-4
PVC (Plastic carrier board)	17.0	9002-86-2
Suction plate	7.5	N/A
Nitrocellulose membrane	1.5	N/A
Glass cellulose membrane	1.5	N/A
Chloroauric acid	1.0	16903-35-8

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Version: 1.0

Initial Date: Sept. 07, 2020

Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Component(s)	Content, %	CAS No.
Poly(ethylene glycol) 20000	0.5	25322-68-3
Trehalose	0.5	99-20-7
Sodium phosphate monobasic	0.5	7558-80-7
Sodium phosphate dibasic dodecahydrate	0.5	10039-32-4
Sodium chloride	0.5	7647-14-5
Boric acid	0.5	11113-50-1
Sodium tetraborate	0.5	1330-43-4
Polysorbate 20	0.5	9005-64-5
Sucrose	0.5	57-50-1
Surfactant S7	0.5	N/A
Surfactant S9	0.5	N/A
PVP-40	0.5	9003-39-8
SDS-L	0.5	2386-53-0
MES	0.5	145224-94-8
Optimizer L-30	0.5	N/A
Proclin 300(P-300)	0.5	N/A
Bovine albumin	0.5	9048-46-8
TRIS	0.5	77-86-1
Chemical name	0.5	584-08-7
Potassium carbonate	0.5	N/A
Newborn-Calf Serum	0.5	N/A
SARS-CoV-2 Recombinant protein	0.5	N/A
Goat anti mouse IgG antibody	0.5	N/A

Section 4

First Aid Measures

Description of first aid measures

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

General advice:	Show this material safety data sheet to the doctor in attendance. After receiving the first-aid measure required, consult a physician if necessary.
Skin contact:	It is harmless if used as intended. If skin contact melts, flush cooling with plenty of water. Non medical staff to assist, do not remove the wound cured resin. Consult a physician.
Eyes contact:	If the mucous membrane of the eye or the like is irritated by fumes, steam, fine particles, etc., check for and remove any contact lenses, Occasionally lifting the upper and lower eyelids. Immediately flush eyes with running water, disappear until the chemical residues so far. Provide a readily-accessible eyewash facility and quick-drench safety shower. Do not rubbing eyes with hand.
Inhalation:	If inhales plenty of steam, power or dust, remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is irregular, provide artificial respiration or oxygen by trained personnel. Get medical attention if adverse health effects persist or are severe.
Ingestion:	If the product is in the form of chip and there is a possibility of swallowing: If swallowed: If swallowed in a large quantity, consult with the physician, though the product is low in oral toxicity.

Most important acute and delayed symptoms/effects

- | | |
|---|--|
| 1 | The most important known symptoms and effects are described in section 2 and/or in section 11. |
|---|--|

Immediate/special treatment

- | | |
|---|---|
| 1 | Continue with first aid measures. Treat symptomatically and supportively. |
| 2 | Symptoms may be delayed. |

Section 5

Firefighting Measures

Extinguishing agent

Suitable extinguishing agents:	Use dry sand, dry chemical or CO ₂ foam extinguishing. Use extinguishing media most appropriate for the surrounding fire.
Unsuitable extinguishing agents:	Do not uses a solid water stream as it may scatter or spread fire.

Special hazards arising from the substance or mixture

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Initial Date: Sept. 07, 2020

Item No.: 20A010A027

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- | | |
|---|--|
| 1 | If this product is involved in a fire, the following can be released: Carbon oxides, sodium oxides, boron oxides, etc. |
|---|--|

Fire precautions and measures

- | | |
|---|--|
| 1 | Firefighters must wear self-contained breathing apparatus, wear full body fire suit, fire extinguishing in the upwind. |
| 2 | As far as possible will be transferred to empty containers from the scene. |
| 3 | Keep the fire water spray containers cooling, until the end of fire. |
| 4 | If the containers in the fire ground have been color, must be evacuated immediately. |
| 5 | Isolated accident scene, prohibit access. |
| 6 | Receiving and processing of fire, to prevent environmental pollution. |

Section 6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- | | |
|---|---|
| 1 | No action shall be taken involving any personal risk or without suitable training. |
| 2 | Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. |
| 3 | Do not touch or walk through spilt material, avoid slipping. |
| 4 | Avoid breathing dusts. |
| 5 | Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. |
| 6 | Put on appropriate personal protective equipment (see section 8). |

Environmental precautions

- | | |
|---|---|
| 1 | Prevent further leakage or spillage if safe to do so. |
| 2 | Discharge into the environment must be avoided. |

Methods and materials for containment and cleaning up

- | | |
|---|---|
| 1 | Pick up and arrange disposal without creating dust. Collect mechanically. Keep in suitable, closed containers for disposal. |
| 2 | Disposal: Contaminated material must be disposed of in accordance with all State and/or Local regulations. |

Section 7 Handling and Storage

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Version: 1.0

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Precautions for safe handling

1	Put on appropriate personal protective equipment (see section 8).
2	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.
3	Workers should wash hands and face before eating, drinking and smoking. Avoid contact eyes. Avoid formation of dust and aerosols.
4	Provide suitable exhaust equipment. Operate in a well-ventilated place.
5	Normal measures for preventive fire protection. Keep away from heat/sparks/open flames/hot surfaces.
6	Observe good housekeeping procedures and hygiene practices.
7	Handling carefully to prevent damage the packaging and container.
8	Wash thoroughly after handling.
9	Persons with a history of skin sensitization problems should not be employed in any process in which this product is used.
10	Equipped with corresponding varieties and number of fire equipment and spill contingency processing equipment.

Precautions for storage

1	Store in accordance with local regulations. Stored in a dry, cool and well-ventilated area. Keep container tightly closed.
2	Keep away from sparks, open flames and high temperatures, away from incompatible materials (see section 10).
3	Keep out of reach children and pets.

Section 8

Exposure Controls/Personal Protection

Control parameters

Occupational Exposure limit values

Components CAS No.	Country/region	Occupational exposure limits (8h)		Occupational exposure limits (Short time)	
		ppm	mg/m ³	ppm	mg/m ³
Ethanol	USA-NIOSH	-	1	-	-
Sodium	Korea	-	1	-	-

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Version: 1.0	Initial Date: Sept. 07, 2020	Item No.: 20A010A027	MSDS No.: EMS.200.907.018.LMT

tetraborate 1330-43-4	Germany (DFG)	-	0.75	-	0.75
	Denmark	-	1	-	2
	Belgium	-	2	-	6
	Australia	-	1	-	-
Sucrose 57-50-1	USA-OSHA	-	15	-	-
	England	-	10	-	20
	Korea	-	10	-	-
	Ireland	-	10	-	20
	Canada - Ontario	-	10	-	-
	Australia	-	10	-	-
Sodium chloride 7647-14-5	Latvian	-	5	-	-

Engineering controls

- 1 Ensure adequate ventilation, especially in confined areas.
- 2 Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protection

General requirements:	
Respiratory protection:	Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eye protection:	Wear safety glasses when there is a potential for eye contact.
Skin and body protection:	Wear suitable protective clothing and boots.
Hands protection:	Wear protective gloves. Check protective gloves prior to each use for their proper condition. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Section 9 Physical and Chemical Properties

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Information on basic physical and chemical properties

Appearance and character:	White rectangular solid
Odor:	Odorless
Odor threshold:	No data
Melting point/freezing point (°C):	No data
Initial boiling point and boiling range (°C):	No data
Flash point (°C):	Not applicable
Evaporation rate:	No data
Steam pressure (20°C):	No data
Relative density (water=1):	No data
Partition coefficient: n-octanol/water:	No data
Decomposition temperature (°C):	No data
Auto ignition temperature (°C):	No data
pH value:	No data
Explosion limit [% (v/v)]:	No data
Relative vapor density (air=1):	No data
Solubility:	Insoluble in water
Flammability (solid, gas):	Non flammable
Oxidizing properties:	The substance does not belong to oxidizing substances

Section 10 Stability and Reactivity

Stability and Reactivity

Stability:	The product is chemically stable.
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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Reactivity:	Stable under recommended storage and handling conditions.
Incompatible materials:	Strong oxidizing agents.
Conditions to avoid:	In contrast to the nature of the material, direct sunlight, high temperature and open fire
Hazardous decomposition products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 Toxicological Information

Acute toxicity

Component(s)	CAS No.	LD ₅₀ (Oral)	LD ₅₀ (Dermal)	LC ₅₀ (Inhalation)
Poly(ethylene glycol) 20000	25322-68-3	Rate: 44200mg/kg Rabbit: 28900mg/kg	No data	No data
Sodium phosphate monobasic	7558-80-7	Rate: 8290mg/kg	No data	No data
Sodium chloride	7647-14-5	Rate: 3000mg/kg Mouse: 4000mg/kg	Rabbit: >10000mg/kg	Rate: >42000mg/m ³ /1H
Polysorbate 20	9005-64-5	Rate: >33000mg/kg	No data	No data
Sucrose	57-50-1	Rate: 29700mg/kg	No data	No data
PVP-40	9003-39-8	Rate: 3000mg/kg	No data	No data
TRIS	77-86-1	Rate: 5900mg/kg	No data	No data
Potassium carbonate	584-08-7	Rate: 1870mg/kg Mouse: 2750mg/kg	No data	No data

Skin corrosion/irritation

Component(s)	CAS No.	Species	Route	Value	Result	Type of test
Poly(ethylene glycol) 20000	25322-68-3	Rabbit	Skin	500mg/24H	Mild	Standard Draize test
Sodium chloride	7647-14-5	Rabbit	Skin	500mg/24H	Mild	Standard Draize test

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Eye corrosion/irritation

Component(s)	CAS No.	Species	Route	Value	Result	Type of test
Poly(ethylene glycol) 20000	25322-68-3	Rabbit	Eye	500mg/24H	Mild	Standard Draize test
Sodium chloride	7647-14-5	Rabbit	Eye	100mg/24H	Moderate	Standard Draize test

Respiratory sensitization:	These products are not known to cause human respiratory sensitization.
Skin sensitization:	These products are not known to cause skin sensitization.
Germ cell mutagenicity:	According to the existing data, the product is not classified.
Carcinogenicity:	No classification data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.
Reproductive toxicity:	According to the existing data, the product is not classified.
Specific target organ toxicity - single exposure:	According to the existing data, the product is not classified.
Specific target organ toxicity - repeated exposure:	According to the existing data, the product is not classified.
Aspiration hazard:	According to the existing data, the product is not classified.
Additional reproductive toxicity hazards:	According to the existing data, the product is not classified.

Section 12 Ecological Information

Aquatic toxicity

Acute/Chronic aquatic toxicity:	This product contains no hazardous or toxic substances, and presents a negligible impact on the environment based on its reported use pattern.
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Persistence and degradability

Persistence:	No data.
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Bioaccumulative potential

Bioaccumulation:	The potential for bioaccumulation of this material in aquatic organisms is low.
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Version: 1.0

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

Mobility in soil

Mobility: No data.

Results of PBT and vPvB assessment

Component(s)	CAS No.	Results of PBT and vPvB assessment
Test strip shell (Hydrophobic hard card)	65996-61-4	Not belong to PBT/vPvB
PVC (Plastic carrier board)	9002-86-2	Not belong to PBT/vPvB
Chloroauric acid	16903-35-8	Not belong to PBT/vPvB
Poly(ethylene glycol) 20000	25322-68-3	Not belong to PBT/vPvB
Trehalose	99-20-7	Not belong to PBT/vPvB
Sodium phosphate monobasic	7558-80-7	Not belong to PBT/vPvB
Sodium phosphate dibasic dodecahydrate	10039-32-4	Not belong to PBT/vPvB
Sodium chloride	7647-14-5	Not belong to PBT/vPvB
Boric acid	11113-50-1	Not belong to PBT/vPvB
Sodium tetraborate	1330-43-4	Not belong to PBT/vPvB
Polysorbate 20	9005-64-5	Not belong to PBT/vPvB
Sucrose	57-50-1	Not belong to PBT/vPvB
PVP-40	9003-39-8	Not belong to PBT/vPvB
SDS-L	2386-53-0	Not belong to PBT/vPvB
MES	145224-94-8	Not belong to PBT/vPvB
Bovine albumin	9048-46-8	Not belong to PBT/vPvB
TRIS	77-86-1	Not belong to PBT/vPvB
Chemical name	584-08-7	Not belong to PBT/vPvB

Section 13

Disposal Considerations

Waste disposal

Residual waste:

Before disposal should refer to the relevant national and local laws and regulation.

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Version: 1.0

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Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

	The generation of waste should be avoided or minimized wherever possible. Recommended ignition under control or transfer to a suitable container and arrange for collection by specialized disposal company if recycling is not feasible.
Contaminated packaging:	The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
Disposal considerations:	Dispose of container and unused contents in accordance with national and local relevant regulations laws.

Section 14 Transport Information

Transport rules

According to IATA DGR 61st Edition for transportation, IMO International Maritime Dangerous Goods Code (Amendment 39-18), European Agreement Concerning the International Carriage of Dangerous Goods by Road. The products are not subject to IATA DGR, IMDG and ADR/RID.

Label(s) required

Label(s): None

Road transport (UN-ADR)

UN number: Not regulated

UN proper shipping name: Not regulated

Transport hazard class(es)-Main: Not regulated

Transport hazard class(es)-Sub risk: None

Packaging group: Not regulated

Special provisions: None

Hazard code: None

Air transport (ICAO-IATA/DGR)

UN number: Not regulated

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Version: 1.0	Initial Date: Sept. 07, 2020	Item No.: 20A010A027	MSDS No.: EMS.200.907.018.LMT

UN proper shipping name:	Not regulated
Transport hazard class(es)-Main:	Not regulated
Transport hazard class(es)-Sub risk:	None
Packaging group:	Not regulated
Special provisions for transportation:	None
ERG code:	None

Sea transport (IMDG-CODE)

UN number:	Not regulated
UN proper shipping name:	Not regulated
Transport hazard class(es)-Main:	Not regulated
Transport hazard class(es)-Sub risk:	None
Packaging group:	Not regulated
Special provisions for transportation:	None
Marine pollutants (Yes/No):	No
EmS No.:	None

Section 15 Regulatory Information

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

Regulatory information: Reference to the local, national, US, EU, CA and international regulations.

CAS No.	TSCA	IECSC	EINECS/ELINCS/NLP	DSL/NDSL
65996-61-4	Listed	Listed	Listed	Listed DSL

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Version: 1.0

Initial Date: Sept. 07, 2020

Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

CAS No.	TSCA	IECSC	EINECS/ELINCS/NLP	DSL/NDSL
9002-86-2	Listed	Listed	Listed	Listed DSL
16903-35-8	Listed	Listed	Listed	Listed DSL
25322-68-3	Listed	Listed	Listed	Listed DSL
99-20-7	Listed	Listed	Listed	Listed DSL
7558-80-7	Listed	Listed	Listed	Listed DSL
10039-32-4	Unlisted	Listed	Listed	Listed NDSL
7647-14-5	Listed	Listed	Listed	Listed DSL
11113-50-1	Listed	Listed	Listed	Listed DSL
1330-43-4	Listed	Listed	Listed	Listed DSL
9005-64-5	Listed	Listed	Listed	Listed DSL
57-50-1	Listed	Listed	Listed	Listed DSL
9003-39-8	Listed	Listed	Listed	Listed DSL
2386-53-0	Listed	Listed	Listed	Listed NDSL
145224-94-8	Unlisted	Listed	Listed	Listed NDSL
9048-46-8	Listed	Listed	Listed	Listed DSL
77-86-1	Listed	Listed	Listed	Listed DSL
584-08-7	Listed	Listed	Listed	Listed DSL

Section 16 Other Information

Abbreviations or phrases

ACGIH:	American Conference of Governmental Industrial Hygienists
ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service
CLP:	Classification, labeling and packaging
EC:	Council of Europe

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Version: 1.0 Initial Date: Sept. 07, 2020 Item No.: 20A010A027 MSDS No.: EMS.200.907.018.LMT

ECHA:	European Chemicals Agency
EINECS:	European Inventory of Existing commercial Chemical Substances
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
IARC:	International Agency for Research on Cancer
IATA:	International Air Transport Association
RID:	Regulation for rail International transportation of Dangerous goods
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Dangerous Goods Code
IC ₅₀ :	Inhibitory Concern Triton 50%
LC ₅₀ :	Lethal Concentration 50%
LD ₅₀ :	Median Lethal Dose 50%
MAPROL:	International Convention for the Prevention of Pollution from Ships
REACH:	REGULATION concerning the Registration, Evaluation, Authorization and Restriction of Chemicals
STEL:	Short Term Exposure Limit
TWA:	Time Weighted Average
MAC:	Maximum Allowable Concentration
OSHA:	Occupational Safety and Health Administration
NIOSH:	National Institute for Occupational Safety and Health
TLV:	Threshold Limit Value
TLV-TWA:	Threshold Limit Value-Time Weighted Average
TLV- STEL:	Threshold Limit Value-Short term Exposure Limit
PC-TWA:	Permissible Concentration-Time Weighted Average
PC-STEEL:	Permissible Concentration-Short Term Exposure Limit
PEL:	Permissible Exposure Limit
OELs:	Occupational Exposure Limits

Reference

1	IARC
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Initial Date: Sept. 07, 2020

Item No.: 20A010A027

MSDS No.: EMS.200.907.018.LMT

2	OECD: The Global Portal to Information on Chemical Substances
3	U.S. Department of Transportation: ERG
4	Germany GESTIS-database on hazard substance
5	CAMEO Chemicals
6	NLM: ChemIDplus
7	EPA: Integrated Risk Information System
8	IPCS: The International Chemical Safety Cards (ICSC)

Disclaimer

1	The above information is believed to be correct but we can not guarantee the absolute universality and accuracy and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.
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