

### cobas PCR Media Uni Swab Sample Kit

Version	
1.4	

Revision Date: 06-21-2024

Date of last issue: 10-31-2021 Date of first issue: 09-19-2018

#### **SECTION 1. IDENTIFICATION**

Product name	:	cobas PCR Media Uni Swab Sample Kit

Product code : 07958030190

#### Manufacturer or supplier's details

Company name of supplier	:	Roche Diagnostics Deutschlan	d GmbH
Address	:	116 Sandhoferstrasse Mannheim, 68305 Deutschland	
Telephone Telefax E-mail address Emergency telephone	:	+496217590 +496217592890 info.dia-sds@roche.com	
Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH	+49(0)621-759-2203
Giftnotruf:	:	Mainz	+49(0)6131-19240

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

Recommended use	:	Laboratory chemicals
		Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

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

Acute toxicity (Oral)	:	Category 4
Skin irritation	:	Category 2
Eye irritation	:	Category 2A
GHS label elements Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H302 Harmful if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation.



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Prevention: P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this prod P280 Wear protective gloves/ eye protection/ face pro	
Response: P301 + P312 + P330 IF SWALLOWED: Call a POISO CENTER/ doctor if you feel unwell. Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of soap a P305 + P351 + P338 IF IN EYES: Rinse cautiously wi for several minutes. Remove contact lenses, if presen to do. Continue rinsing. P332 + P313 If skin irritation occurs: Get medical advi tion. P337 + P313 If eye irritation persists: Get medical advi tion. P362 Take off contaminated clothing and wash before	and water. th water at and eas ice/ atten- vice/ atten
<b>Disposal:</b> P501 Dispose of contents/ container to an approved v posal plant.	vaste dis-
P501	Dispose of contents/ container to an approved w

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

<b>•</b> • • • •		
Substance /	Muvturo	
Substance /	IVIIALUIG	

#### Components

Chemical name	CAS-No.	Concentration (% w/w)		
Guanidine, hydrochloride (1:1)	50-01-1	>= 30 - < 50		
Actual concentration is withheld as a trade secret				

#### SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Show this material safety data sheet to the doctor in atten- dance. Do not leave the victim unattended.
If inhaled	:	Move to fresh air. Consult a physician after significant exposure. If unconscious, place in recovery position and seek medical advice.
In case of skin contact	:	If skin irritation persists, call a physician. If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses.



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		Protect unharmed Keep eye wide op If eye irritation per	
If swallowed	:	Keep respiratory t Do not give milk o Never give anythir	r alcoholic beverages. ng by mouth to an unconscious person. st, call a physician.
Most important symptor and effects, both acute delayed		Harmful if swallow Causes skin irritat Causes serious ey	ion.
Notes to physician	:		dure should be established in consultation sponsible for industrial medicine.

#### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	No information available.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Ammonia Gaseous hydrogen chloride (HCl).
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	:	Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.



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#### SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	Avoid formation of aerosol. Do not breathe vapors/dust. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the ap- plication area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated pla- ce. Electrical installations / working materials must comply with the technological safety standards.
Further information on stor- age conditions	:	See label, package insert or internal guidelines
Further information on stor- age stability	:	No decomposition if stored and applied as directed.

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters Contains no substances with occupational exposure limit values.				
Engineering measures	:	No data available		
Personal protective equipn	nent			
Respiratory protection		In the case of vapor formation use a respirator with an approved filter.		
Hand protection				
Material	:	Protective gloves		
Remarks	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.		
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.		
Skin and body protection	:	Impervious clothing Choose body protection according to the amount and con-		



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		f the dangerous substance at the work place.
Hygiene measures	When using	do not eat or drink. do not smoke. s before breaks and at the end of workday.
SECTION 9. PHYSICAL A	ND CHEMICAL PROPE	RTIES
Appearance	: liquid	
Color	: colorless	
Odor	: No data av	ailable
Odor Threshold	: No data av	ailable
рН	: 7.3 - 7.7 Concentrat	ion: 100 %
Melting point/range	: -9 - 16 °F /	-239 °C
Boiling point/boiling ra	ange : 208 - 219 °	F / 98 - 104 °C
Flash point	: does not fla	ash
Evaporation rate	: No data av	ailable
Flammability (solid, ga	as) : Does not s	ustain combustion.
Flammability (liquids)	: Does not s	ustain combustion.
Self-ignition	: Not applica	ble
Upper explosion limit / flammability limit	/ Upper : No data av	ailable
Lower explosion limit / flammability limit	/ Lower : No data av	ailable
Vapor pressure	: No data av	ailable
Relative vapor density	/ : No data av	ailable
Relative density	: No data av	ailable
Density	: 1,097 g/cm	3 (68 °F / 20 °C)
Solubility(ies) Water solubility	: completely	miscible



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Solubility in other solvents	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac- tions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	Temperatures greater than recommended storage temperatu- re.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

#### SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity Harmful if swallowed.		
Product:		
Acute oral toxicity	:	Acute toxicity estimate: 1,300 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 8.75 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method



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Components:			
Guanidine, hydro	ochloride (1:1):		
Acute oral toxicity		Rat, female): 475 mg/kg	

	GLP: yes
Acute inhalation toxicity :	LC50 (Rat, female): 3.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 GLP: yes LC50 (Rat, male and female): 5.32 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403
	GLP: yes

LC50 (Rat, male): 7.7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: yes

Method: OECD Test Guideline 401

 Acute dermal toxicity
 : LD50 Dermal (Rabbit, male and female): > 2,000 mg/kg

 Method: OECD Test Guideline 402

 GLP: yes

 Assessment: The substance or mixture has no acute dermal toxicity

 Remarks: No mortality observed at this dose.

#### Skin corrosion/irritation

Causes skin irritation.

#### Product:

Remarks : May cause skin irritation in susceptible persons.

#### Components:

Guanidine, hydrochloride (1:1):		
Species	:	Rabbit
Exposure time	:	24 h
Result	:	Irritating to skin.
GLP	:	yes

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Product:

Remarks

: May cause irreversible eye damage.



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#### Components:

#### Guanidine, hydrochloride (1:1):

Species	:	Rabbit
Result	:	Irritating to eyes.
Method	:	OECD Test Guideline 405
GLP	:	yes

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

#### Respiratory sensitization

Not classified due to lack of data.

#### **Components:**

#### Guanidine, hydrochloride (1:1):

Test Type	:	Buehler Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
GLP	:	yes

#### Germ cell mutagenicity

Not classified due to lack of data.

#### Components:

#### Guanidine, hydrochloride (1:1):

Genotoxicity in vitro	<ul> <li>Test Type: Microbial mutagenesis assay (Ames te Test system: Salmonella typhimurium Metabolic activation: with and without metabolic ac Method: OECD Test Guideline 471 Result: negative GLP: yes</li> </ul>	,
	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster fibroblasts Method: OECD Test Guideline 473 Result: negative	

GLP: no

#### Carcinogenicity

Not classified due to lack of data.

- **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.



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#### Reproductive toxicity

Not classified due to lack of data.

#### Components:

#### Guanidine, hydrochloride (1:1):

Effects on fetal development :

Species: Rat, female Application Route: Oral Dose: 50, 150, 350 mg/kg bw/day Duration of Single Treatment: 5 - 19 d Developmental Toxicity: NOAEL: 350 mg/kg body weight Method: OECD Test Guideline 414 GLP: yes

#### STOT-single exposure

Not classified due to lack of data.

#### STOT-repeated exposure

Not classified due to lack of data.

#### **Repeated dose toxicity**

#### Components:

#### Guanidine, hydrochloride (1:1):

Species	:	Rat, male and female
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Dose	:	25, 100, 300 mg/kg bw/day
Method	:	OECD Test Guideline 408
GLP	:	yes
Exposure time Dose Method	:	90 d 25, 100, 300 mg/kg bw/day OECD Test Guideline 408

#### Aspiration toxicity

Not classified due to lack of data.

#### **SECTION 12. ECOLOGICAL INFORMATION**

#### Ecotoxicity

**Components:** 

Guanidine, hydrochloride (1:1)	:
Toxicity to fish :	LC50 (Leuciscus idus (Golden orfe)): 1,758 mg/l End point: mortality Exposure time: 48 h Test Type: static test GLP: yes
Toxicity to daphnia and other : aquatic invertebrates	EC50 (Daphnia magna (Water flea)): 70.2 mg/l End point: Immobilization Exposure time: 48 h



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			Test Type: stati Analytical moni Method: OECD GLP: No inform	toring: yes Test Guideline 202
	Toxicity to algae/aquatic plants	:	mg/l End point: Grov Exposure time: Test Type: stati Analytical moni	72 h c test
			mg/l Exposure time: Test Type: stati Analytical moni	c test
			mg/l End point: Grov Exposure time: Test Type: stati Analytical moni	72 h c test
	Toxicity to fish (Chronic tox- icity)	:	End point: mort Exposure time: Test Type: flow Analytical moni	35 <sup>°</sup> d -through test toring: yes Test Guideline 210
	Toxicity to daphnia and othe aquatic invertebrates (Chror ic toxicity)		End point: repro Exposure time: Analytical moni	21 d toring: yes Test Guideline 211
	Toxicity to microorganisms	:	EC10 (Pseudor End point: Grov Exposure time: Test Type: stati Method: DIN 38 GLP: yes	18 h c test



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#### **Ecotoxicology Assessment**

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

#### Persistence and degradability

#### Components:

#### Guanidine, hydrochloride (1:1):

Biodegradability :	aerobic Inoculum: activated sludge, adapted Concentration: 10 mg/l Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 33 d Method: OECD Test Guideline 301C GLP: yes
Impact on Sewage Treat- : ment	Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

#### **Bioaccumulative potential**

#### **Components:**

#### Guanidine, hydrochloride (1:1):

Partition coefficient: n-	:	log Pow: < -1.7 (68 °F / 20 °C)
octanol/water		pH: 7.4
		Method: OECD Test Guideline 107
		GLP: ves

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#### Mobility in soil

No data available

#### Other adverse effects

#### Product:

Ozone-Depletion Potential

Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).



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#### SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not contaminate ponds, waterways or ditches with chemi- cal or used container. Send to a licensed waste management company. Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	:	Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

#### **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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable

#### **Domestic regulation**

49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Remarks

Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

#### **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

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

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#### 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 : Acute toxicity (any route of exposure) Skin corrosion or irritation



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Serious eye damage or eye irritation

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.

#### **Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Water	7732-18-5
Guanidine, hydrochloride (1:1)	50-01-1

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### The ingredients of this product are reported in the following inventories:

AIIC	:	On the inventory, or in compliance with the inventory
DSL	:	All components of this product are on the Canadian DSL
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	On the inventory, or in compliance with the inventory
ISHL	:	On the inventory, or in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory



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PICCS	: On the inventory	, or in compliance with the inventory

IECSC :	On the inventory, or in compliance with the inventory
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- TCSI : On the inventory, or in compliance with the inventory
- TSCA : All substances listed as active on the TSCA inventory

TECI	:	Not in compliance with the inventory
-		

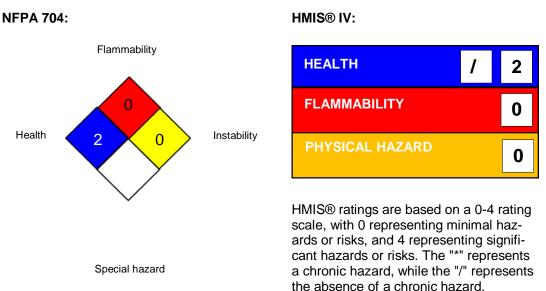
#### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### SECTION 16. OTHER INFORMATION

#### **Further information**



#### Full text of other abbreviations

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 Standardisation; 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% response; EHS - Extremely Hazardous Gubth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -



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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; 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, Authorisation 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; 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

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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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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