



cobas PCR Urine 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 Urine Sample Kit
Product code : 05170486190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-
Address : 9115 Hague Road
Indianapolis, IN 46250
USA
Telephone : 1-800-428-5074
Emergency telephone
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

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.

Precautionary Statements : **Prevention:**
P264 Wash skin thoroughly after handling.



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P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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 attendance.
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.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.



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- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : 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 circumstances 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, protective equipment and emergency 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.

SECTION 7. HANDLING AND STORAGE



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- 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 application 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 place.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage 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 equipment

- 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 concentration of the dangerous substance at the work place.
- Hygiene measures : When using do not eat or drink.
When using do not smoke.



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Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid

- Color : colorless

- Odor : No data available

- Odor Threshold : No data available

- pH : 7.3 - 7.7
Concentration: 100 %

- Melting point/range : -9 - 16 °F / -23 - -9 °C

- Boiling point/boiling range : 208 - 219 °F / 98 - 104 °C

- Flash point : does not flash

- Evaporation rate : No data available

- Flammability (solid, gas) : Does not sustain combustion.

- Flammability (liquids) : Does not sustain combustion.

- Self-ignition : Not applicable

- Upper explosion limit / Upper flammability limit : No data available

- Lower explosion limit / Lower flammability limit : No data available

- Vapor pressure : No data available

- Relative vapor density : No data available

- Relative density : No data available

- Density : 1,097 g/cm³ (68 °F / 20 °C)

- Solubility(ies)
 - Water solubility : completely miscible

 - Solubility in other solvents : No data available

- Partition coefficient: n- : No data available



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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 reactions : No decomposition if stored and applied as directed.

Conditions to avoid : Temperatures greater than recommended storage temperature.

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

Components:

Guanidine, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 475 mg/kg
Method: OECD Test Guideline 401
GLP: yes



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- 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
- 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.

Components:

Guanidine, hydrochloride (1:1):

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



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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 : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

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.

Reproductive toxicity

Not classified due to lack of data.



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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

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 : EC50 (Daphnia magna (Water flea)): 70.2 mg/l
aquatic invertebrates : End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: No information available.



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Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 33.5 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: Regulation (EC) No. 440/2008, Annex, C.3
 GLP: yes

EC50 (Pseudokirchneriella subcapitata (green algae)): 11.8 mg/l
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: Regulation (EC) No. 440/2008, Annex, C.3
 GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 6.3 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: Regulation (EC) No. 440/2008, Annex, C.3
 GLP: yes

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 181 mg/l
 End point: mortality
 Exposure time: 35 d
 Test Type: flow-through test
 Analytical monitoring: yes
 Method: OECD Test Guideline 210
 GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 2.9 mg/l
 End point: reproduction rate
 Exposure time: 21 d
 Analytical monitoring: yes
 Method: OECD Test Guideline 211
 GLP: No information available.

Toxicity to microorganisms : EC10 (Pseudomonas putida): 7,125 mg/l
 End point: Growth rate
 Exposure time: 18 h
 Test Type: static test
 Method: DIN 38 412 Part 8
 GLP: yes

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.



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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 Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

Bioaccumulative potential

Components:

Guanidine, hydrochloride (1:1):

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

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.



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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.

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
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.



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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 SOCM 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.

Pennsylvania Right To Know

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
- PICCS : On the inventory, or in compliance with the inventory
- IECSC : On the inventory, or in compliance with the inventory
- TCSI : On the inventory, or in compliance with the inventory

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- TSCA : All substances listed as active on the TSCA inventory
- TECI : Not in compliance with the inventory

TSCA list

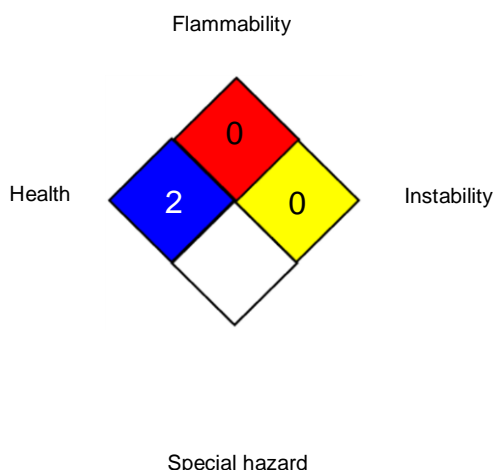
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	/	2
FLAMMABILITY	0	
PHYSICAL HAZARD	0	

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

Full text of other abbreviations

AICC - 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% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to



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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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