

67619-12

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

October 2, 2006

Janet Martinez
Clorox Professional Products Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

Subject: CPPC Tsunami
EPA Registration No. 67619-12
Application Date: May 19, 2006
Receipt Date: May 23, 2006

Dear Ms. Martinez:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

The proposed label claims that the product, CPPC Tsunami, is an effective disinfectant on hard, non porous surfaces against Norwalk virus (as Feline calicivirus) in the presence of a 5% organic soil load for a contact time of 1 minute.

Conditions

1. The proposed label claims that the product, Tsunami, is an effective disinfectant on hard, non-porous surfaces against Bird Flu (Avian Influenza A) in the presence of a 5% organic soil load when used at full strength for a contact time of 1 minute (towelette application). This claim is unacceptable.

Although, the product demonstrated effectiveness against Avian Influenza (A)(H3N2), pump spray or other similarly ready-to-use (RTU) package products do not adequately deliver the volume of liquid required to disinfectant sites likely to be contaminated with avian influenza (i.e., poultry and/or farm premises).

2. Move the use site "gurneys" found on page 5 in table 1 to a new line.

3. The word "**bird flu**" must be deleted from the proposed label. This term too general of a descriptor. Product users are likely to presume that product efficacy has been demonstrated using highly pathogenic forms of the Avian Influenza virus.
4. Remove the unsubstantiated claim "A Clorox breakthrough in [medical/dental/veterinary/health care] bleach disinfection."
5. Remove the implied safety claim "Soft hand feel" from the label.
6. The comparative claim "[Clorox] essential for the purest clean is unacceptable and has been removed from the proposed label.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager – Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

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ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT - 2 2006

For the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

67619-12

CPPPC

Tsunami

ACTIVE INGREDIENT:

Sodium Hypochlorite 0.55%^[†]

Other Ingredients: 99.45%

Total: 100.00%

(Yields 5.84% available chlorine)

58,425 PPM [Parts Per Million] available chlorine

[†] Does not include weight of dry wipe.)

KEEP OUT OF REACH OF CHILDREN CAUTION:

Liquid causes moderate eye irritation.
See back label for additional precautionary statements

Additional statement for single count wipe pouch:
See carton for additional directions for use.

Net content _____ Premoistened Wipes

Clorox Customer Assistance 1-888-797-7225. Any Questions? The experts at Clorox are standing by to answer any of your questions -or- Questions or Comments? Call (toll-free) 1-888-797-7225. Satisfaction Guaranteed! [†] At Clorox we have prided ourselves in making consistent quality products (for over 75 -or- years), and we are dedicated to ensuring your total satisfaction with our product. If you are not completely satisfied, please call the number below -or- 1-888-797-7225. For MSDS information please go to www.cloroxprofessional.com

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Made In the USA

EPA Reg. No. 67619-12

EPA Est. No. 5813-CA-03, CA-04, GA-01, 2688-WI-08, 6251-WI-01, WI-02, WI-03, WI-04, WI-05. Actual EPA Est. No. near batch code

Visit us at www.cloroxprofessional.com

For use with basic formula and alternates A02, A04, A06, A08 and A10. Contains no phosphorus.

R0618-7.1

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Liquid causes moderate eye irritation. Do not get in eyes or on clothing. Avoid contact with clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. [[For sensitive skin or prolonged use,] wear gloves.]

FIRST AID: If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For further information, call 1-888-797-7225. -or- Questions? Call 1-888-797-7225.

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not use this product with other chemicals such as ammonia, toilet bowl cleaners, rust removers, or acid, as this releases hazardous gases. [Avoid contact with clothes, fabric, wood, rubber, painted and paper surfaces. Do not use on aluminum, silver or chipped enamel. **APPLY CAREFULLY** - This product contains bleach.]

STORAGE AND DISPOSAL:

STORAGE: Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration.

DISPOSAL: Dispose of wipe in trash after use. Do not flush. Do not reuse empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Not for cleaning or sanitizing skin. Do not use as a diaper wipe or for personal cleansing.
For surfaces that may come in contact with food, a potable water rinse is required.

DISPENSER DIRECTIONS: Remove lid and discard seal. Insert corner of center sheet through flap opening on lid. DO NOT push finger through opening. Replace lid and pull wipe at an angle. The next sheet pops up automatically. When finished, close lid flap to retain moisture.

TO OPEN PACKAGE: [Open lid and] pull out wipe from center of roll. [The] next sheet pops up automatically. [When finished] close lid to retain moisture.

DISINFECTION

TO [CLEAN AND] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: Wipe [hard, nonporous] surface to be disinfected. Use enough wipes for treated surface to remain visibly wet for the contact time listed below -or- on label. [Rinse.] Let air dry. Gross filth should be removed prior to disinfecting. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel after appropriate contact time has expired.]

Pathogen:	Bacteria	† Viruses	‡ Bloodborne Pathogens	TB	Parvoviruses	Mold/Mildew/Fungi
Contact Time:	30 seconds*	1 minute	1 minute	2 minutes	5 minutes	5 minutes

-and/or-

ORGANISMS:

Bacteria:

- *Enterococcus faecalis, vancomycin resistant (VRE) [ATCC 51575]*
- *Escherichia coli (E. coli) [ATCC 11229]*
- *Klebsiella pneumoniae [ATCC 4352]*
- *Legionella pneumophila [ATCC 33153]*
- *Listeria monocytogenes [ATCC 19117]*
- *Pseudomonas aeruginosa [ATCC 15442]*
- *Salmonella choleraesuis [ATCC 10708]*
- *Shigella dysenteriae [ATCC 11835]*
- *Staphylococcus aureus [ATCC 6538]*
- *Staphylococcus aureus, methicillin resistant (MRSA) [ATCC 33592]*
- *Streptococcus pneumoniae [ATCC 6305]*
- *Streptococcus pyogenes [ATCC 12344]*

Clostridium difficile (Vegetative Form)[†]
[ATCC 9689]**

[†] Killing the vegetative cells can help reduce the bioburden of Clostridium difficile on environmental surfaces

Viruses Non-enveloped:

- *Adenovirus type 2 [ATCC VR-846]
[(Strain Adenoid 6)]**
[(common cause of respiratory infections)]
- *Human Hepatitis A [(Strain HM-175)]**
- *Norwalk virus [(as Feline Calicivirus)] [ATCC VR-782]**
- *Poliovirus type 1 [ATCC VR-1000]
[(Strain Brunhilde)]**
- *Rhinovirus type 37 [ATCC VR-1147]
[(Strain 151-1)]**
[(leading) causative agent of the common cold)]
- *Rotavirus [(Strain WA)]**
[(causative agent of viral diarrhea)]

Viruses Enveloped:

- *Herpes simplex virus type 2 [ATCC VR-734]
[(Strain G)]**
[(causative agent of genital herpes)]
- *HIV type 1 [(Strain HTLV-IIIB)]*
- *Human Coronavirus [ATCC VR-740]
[(Strain 229E)]**
[(additional) causative agent of the common cold)]
- *Human Hepatitis B [(as duck HBV)]**
- *Influenza A [ATCC VR-544] [(Strain Hong Kong)]**
[(representative of the common flu virus)]
- *Respiratory syncytial virus [ATCC VR-26]
[(Strain Long)]**
[(cause of respiratory infections in infants)]

Bloodborne Pathogens:

- *HIV type 1 [(Strain HTLV-IIIB)]*
- *Human Hepatitis B [(as duck HBV)]**

Mycobacterium:

Mycobacterium bovis BCG (Tuberculosis -or- TB)
[OT 105401]***

Parvoviruses Non-enveloped:

- Canine parvovirus [ATCC VR-2017]
[(Strain Cornell)]****
- Feline panleukopenia virus [ATCC VR-648]
[(Strain Phillips-Roxane)]****
[(feline parvovirus)]

Mold, Mildew, Fungi:

Aspergillus niger [ATCC 16404]****
Trichophyton mentagrophytes [ATCC 9533]****

- *30 second contact time
- **1 minute contact time
- ***2 minute contact time
- ****5 minute contact time

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Claims:

- [30 second] broad spectrum no-rinse disinfectant for non-food contact surfaces
- A disinfectant cloth for use on _____ (insert use site(s) from table 1-5)
- [A] one-step cleaner/disinfectant
- Aids in reducing -or- in the reduction of cross-contamination between treated surfaces
- Assures proper dilution strength, product effectiveness and standardizes technique
- Bactericide -or- Bactericidal
- Bathroom disinfectant wipes
- Broad spectrum disinfectant [with Clorox Bleach]
- [Cleans and] disinfects _____ (insert use site(s) from table 1-5)
- [Cleans and] disinfects [hard, nonporous surfaces]
- Cleans, deodorizes and disinfects
- Deodorizes by killing the germs that cause odors
- Disinfecting formula
- Disinfects [and deodorizes]
- Disinfects and deodorizes by killing germs and their odors
- Disinfects hard, nonporous surfaces [throughout the _____ (insert use site(s) from table 1-5)]
- Easy and convenient disinfecting [throughout the _____ (insert use site(s) from table 1-5)]
- Easy, one-step cleaning and disinfecting
- Effective against -or- Kills _____ (Insert any organism(s) from table above) [in the presence of organic soil [(5% blood serum)]]
- Effective against -or- Kills a wide range of bacteria including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* [in the presence of organic soil [(5% blood serum)]]
- [Effectively] disinfects [hard, nonporous] [environmental] surfaces
- Eliminates odors at their source [caused by germs -or- bacteria -and/or- mildew]
- Eliminates -or- Reduces odors [caused by germs -or- bacteria -and/or- mildew]
- Exhibits effective virucidal activity
- Fungicide -or- Fungicidal
- Germicidal disposable wipes
- Germicide -or- Germicidal
- Just wipe to clean and disinfect
- Kills bacteria, viruses, mold, mildew
- Kills many common bacteria and viruses
- Kills odor-causing bacteria -or- germs
- Kills -or- Destroys mold and mildew
- Kills -or- Effective against bacteria
- Kills -or- Effective against germs
- Kills -or- Effective against viruses
- Meets [the disinfection requirements of] OSHA's Bloodborne Pathogen Guidelines -or- Standards
- Mildewicide -or- Mildewicidal
- Multi-purpose disinfectant
- One-step cleaner and disinfectant
- One-step cleaning and disinfecting [saves time]
- One-step disinfectant cleaner designed for general cleaning and disinfecting hard, nonporous environmental surfaces in health care facilities -or- (insert use site(s) from table 1)
- Prevents -or- controls mold and mildew growth
- Pseudomonocidal
- [Ready-to-use] hospital [grade] disinfectant
- Reduces the risk of infection and cross-contamination
- Staphylocidal
- The answer to your disinfecting needs
- The easy, convenient way to clean and disinfect with Clorox Bleach
- [The] quick -and/or- easy -and/or- convenient way to disinfect
- [This product] controls the spread of germs on most hard, nonporous surfaces
- This product meets AOAC efficacy testing requirements -or- standards for hospital disinfection
- Tuberculocide -or- Tuberculocidal
- Use where control of the hazards of cross-contamination between treated surfaces is of prime importance
- Virucide -or- Virucidal

Use Sites: See Tables 1-5.

The following is only for products with medical devices listed on the label:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Special Instructions for Use Against HIV-1

This product kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus (HIV-1) (associated with AIDS).

Special instructions for using this product to clean and decontaminate against HIV-1 on surfaces/objects soiled with blood/body fluids:

Personal Protection: When handling items soiled with blood or body fluids, use disposable impervious gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Allow surfaces to remain wet for 30 seconds, [rinse and] let air dry. For all other organisms, see directions for contact times.

Disposal of Infectious Materials: Use disposable impervious gloves, gowns, masks and eye coverings. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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FARM PREMISE AND POULTRY HOUSE DISINFECTANT (INSTRUCTIONS):

(Directions For Use:)

1. Remove all poultry or animals and feeds from premises, trucks, vehicles, coops, crates, and enclosures.
2. Remove all litter and manure or droppings from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals or poultry.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Wipe all surfaces using enough wipes to keep surfaces visibly wet for 1 minute.
6. Wipe all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

CLEANING AND STAIN REMOVAL

To clean -and/or- remove stains: Wipe surface with a wipe; [rinse and] let air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel.]

Claims:

- Cleans
- Removes _____ (insert stain(s)/soil(s) from table below)
- Removes stains

Stains/Soils:

- | | | | |
|-------------------|--------------------------------|---------------------|--|
| • Blood | • Dirt | • Grease | • [Other] common soils -and/or- stains |
| • Body oils | • Fecal matter | • Grime | • [Other] organic matter |
| • Coffee [stains] | • Fingerprints | • Laboratory stains | • Tea [stains] |
| • Dead skin | • Food residue(s) -or- soil(s) | • Mildew stains | • Urine |
| | • Fruit [stains] | • Mold stains | |

ALLERGEN DESTRUCTION

To [clean and] destroy specified allergens: Wipe surface. Use enough wipes for treated surfaces to remain visibly wet for 1 minute. [Rinse.] Let air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel after contact time has expired.]

Allergens:

- Cockroach matter -or- particles
- Dust mite matter -or- particles
- Pet dander -or- dog and cat dander

Claims:

- Breaks Down Many Allergens[!]
- Destroys Many Allergens[!]
- Destroys -or- deactivates dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust]
- [Penetrates and] breaks down dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust]
- Reduces dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust]
- Reduces Many Allergens[!]
- This product kills germs and destroys many allergens while cleaning hard, nonporous surfaces.

GENERAL CLAIMS

- A solution impregnated in a wiping cloth
- Convenient
- Disposable
- Does not contain mercury
- Does not contain nonylphenol ethoxylates (NPEs) -and/or- alkylphenol ethoxylates (APEs)
- Does not contain VOCs
- Easy and convenient to use
- Easy to handle
- Eliminates airborne particles associated with sprays
- Eliminates [dairy] mixing and measuring
- [For] general use
- For use on bathroom surfaces
- For use on nursery surfaces
- Fresh lingering bleach scent
- Leaves a fresh bleach scent
- Mercury free
- Moist wipes
- No measuring
- No mixing
- Nonylphenol ethoxylate (NPE) -and/or- alkylphenol ethoxylate (APE) free
- Pre-measured
- Pre-moistened [towelettes]
- Ready to use
- Shelf-stable formula
- Specifically -or- Specially designed for the Medical/Dental/Veterinary/Health Care Industry
- [Strong,] [Durable,] cloth-like wipes
- [Strong,] [Durable,] non-woven disposable cloth
- [Strong,] [Durable,] non-woven wipe does not leave lint on surfaces [following use]
- Suitable for hospital use
- [Contains] the power of Clorox Bleach
- [The] smell of clean
- VOC free
- VOC's below laboratory detection limits

R0618-7.1

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SURFACE SAFETY CLAIMS

- Safe for use on _____ (*Insert surface material(s) from table 5*)
- Will not harm [titanium-coated] [medical grade] stainless steel
- Safe on hard, nonporous inanimate environmental surfaces

TABLE ONE Medical:

USE SITES

Ambulances -or- [Emergency Medical] Transport Vehicles
Anesthesia Rooms -or- Areas
[Assisted Living -or- Full Care] Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms -or- Areas
Critical Care Units -or- CCUs
Dialysis Clinics
Emergency Rooms -or- ERs
Health Care Settings -or- Facilities
Home Health Care [Settings]
Hospitals
[Hospital] Kitchens
Intensive Care Units -or- ICUs
Laboratories
[Medical] Clinics
Medical Facilities

Medical -or- Physician's -or- Doctor's Offices
Newborn -or- Neonatal Nurseries
Nursing -or- Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
[Pediatric] Examination Rooms -or- Areas
Pharmacies
Physical Therapy Rooms -or- Areas
Radiology -or- X-Ray Rooms -or- Areas
Recovery Rooms
Respiratory Therapy Rooms -or- Areas
Surgery Rooms -or- Operating Rooms -or- ORs

SURFACES

bed pans
[exam -or- examination] tables
external surfaces of [medical] equipment -or- [medical] equipment surfaces
external [surfaces of] ultrasound transducers ~~gurneys~~
hard, nonporous [environmental] hospital -or- medical surfaces
[hospital -or- patient] bed railings -or- linings -or- frames
IV poles
patient chairs
plastic mattress covers
reception counters -or- desks -or- areas
stretchers
wash basins
wheelchairs
gurneys

TABLE TWO Dental:

USE SITES

Dental Operatories
Dental -or- Dentist's Offices

SURFACES

dental countertops
dental operatory surfaces
dentist -or- dental chairs
hard, nonporous [environmental] dental surfaces
light lens covers
reception counters -or- desks -or- areas

TABLE THREE Veterinary:

USE SITES

Animal Housing Facilities
Animal Life Science Laboratories
[Animal -or- Pet] Grooming Facilities
Equine Farms
Farms
Kennels
Livestock -and/or- Swine -and/or- Poultry Facilities
Pet Areas
Pet Shops -or- Stores
Small Animal Facilities
Veterinary Clinics -or- Facilities
Veterinary Offices
Veterinary -or- Animal Hospitals

SURFACES

animal equipment
automatic feeders
cages
external surfaces of [veterinary] equipment
feed racks
fountains
hard, nonporous [environmental] veterinary surfaces
pens
reception counters -or- desks -or- areas
stalls
troughs
veterinary care surfaces
watering appliances

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TABLE FOUR Food Service:

USE SITES

Bars
Cafeterias
Commercial -or- Institutional Kitchens
Delis
Fast Food Chains -or- Restaurants
Food Preparation and Processing Areas
Food (Service -or- Processing) Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES

any washable (food and non-food contact) surface where disinfection is required
appliances
dish racks
drain boards
food cases
food trays
freezers
hoods
microwaves
outdoor furniture (excluding wood frames and upholstery)
ovens
refrigerators
salad bar sneeze guards
stoves -or- stovetops

A potable water rinse is required for food contact surfaces.
Do not use on glassware, utensils, or dishes.

TABLE FIVE Miscellaneous/General:

USE SITES

Airplanes
Blood Banks
Bowling Alleys
Butcher Shops
Churches
Colleges
Correctional Facilities
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums -or- Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants -or- Facilities
Military Installations
Motels
Produce Areas
Public Areas
Recreational Centers -or- Facilities
Restrooms -or- Restroom Areas
School Buses
Schools
Shelters
Shower Rooms
Storage Rooms -or- Areas
Supermarkets
Trains
Universities

SURFACES

[bathroom] fixtures
[bath]tubs
behind and under counters
behind and under sinks
booster chairs
cabinets
ceilings
cell[ular] -or- wireless -or- mobile -or- digital phones
chairs
[computer] keyboards
[computer] monitors
counters -or- countertops
cribs
desks
[diaper -or- infant] changing tables
diaper pails
dictating equipment [surfaces]
doorknobs
exterior -or- external toilet surfaces
exterior -or- external urinal surfaces
faucets
floors
garbage -or- trash cans
[grocery store -or- supermarket] carts
hampers
hand railings
headsets
highchairs
lamps
linoleum
other telecommunications equipment [surfaces]
playpens
shelves
showers -or- shower stalls
sinks
stall doors
tables
telephones
[tiled] walls
toilet rims
toilet seats
towel dispensers
toys
vanity tops -or- vanities

SURFACE MATERIALS

[baked] enamel
chrome
[common] hard, nonporous [household -or- environmental] surfaces
Formica
glass
glazed ceramic [tile]
glazed porcelain
laminated surfaces
Marlite
plastic [laminite]
porcelain enamel
stainless steel
synthetic marble
vinyl [tile]
similar hard, nonporous surfaces
except for those excluded by the label

Not Recommended For Use On
-or- Avoid contact with:

aluminum
brass
chipped enamel
clear plastic
clothes
copper
fabric
natural marble
painted surfaces
paper surfaces
rubber
sealed granite
silver
unfinished wood
wood