



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 8, 2018

Emily Phalen
Contec Inc.
525 Locust Grove
Spartanburg, SC 29303

Subject: Notification per PRN 98-10 – *re-add the qualification statement: “bacteriostatic activity against odor-causing bacteria for up to 6 months on hard surfaces”*
Product Name: **Sporicidin (Brand) Disinfectant Towelette**
EPA Registration Number: 8383-7
Application Date: 01/02/18
Decision Number: 538289

Dear Ms. Phalen:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Stacey Grigsby".

Stacey Grigsby
Regulatory Risk Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

NOTIFICATION

8383-7

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/08/2018

Sporicidin (Brand) Disinfectant Towelettes (Or alternate brand name)

(Hospital Disinfectant) (Broad Spectrum Disinfectant)(Mold & Mildewcide)(Mildewstat)(Bactericide)(Bacteriostat)(Fungicide)(Fungistat)(Deodorant and Disinfectant)(Antimicrobial)

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL **
- TUBERCULOCIDAL
- PREVENTS MOLD AND MILDEW
- ELIMINATES ODORS (DEODORIZES)
- (FOR USE IN INSTITUTIONAL, INDUSTRIAL, HOUSEHOLD, HEALTH CARE, SPA/RECREATIONAL FACILITIES, FARM PREMISES AND ANIMAL QUARTERS)
- (SPORICIDIN DISINFECTANT TOWELETTES) ARE A BROAD SPECTRUM DISINFECTANT EFFECTIVE AGAINST LISTED VIRUSES, BACTERIA, FUNGI, MOLD & MILDEW. ELIMINATES ODORS CAUSED BY BACTERIA (AND GERMS))
- (KILLS and controls Mold, Mildew, Fungus, and Bacteria)
- (COMMERCIAL MULTI-PURPOSE ANTIMICROBIAL TREATMENT)
- (CLEANS, DISINFECTS, AND DEODORIZES)
- (CLEANER /NEW Only in first 6 months of product existence) (QUICK) (EASY) (EFFECTIVE) (FAST, EFFECTIVE) (CONVENIENT) (CLEANS, DISINFECTS & DEODORIZES)(ALL PURPOSE CLEANER) (DISINFECTANT FORMULA) (CLEANS and DISINFECTS) (DISINFECT AND TOUCH-UP CLEAN ANYTIME)
- (Fresh Scent) (Sparkle Scent) (Clean Breeze Scent) (Orange Ultra Scent) (BioClean Scent) (XXX Scent)
- (BLEACH-FREE)(ALCOHOL-FREE)(O-PHENOL-FREE)(o-phenyl phenol free)
- (Hard Surface Disinfectant)
- (One Step Cleaner, Deodorizer, & Disinfectant)
- (Buffered Phenol)

ACTIVE INGREDIENTS

Phenol1.56%

Sodium Phenate.....0.06%

OTHER INGREDIENTS98.38%

Total 100.00%

EPA REG. NO. 8383-7
EPA EST. NO. (XXXX)
See Batch code for actual Est. No.

Proposed Master Label

KEEP OUT OF REACH OF CHILDREN

CAUTION

See other precautions (on side panel) (below) (on back panel)

NET CONTENTS: (Towelettes (in x in)) (Saturated with disinfectant (lb. fl. oz))

(MFG by:)(Manufactured for:)(Distributed by:)(Insert Company)

CONTEC, INC/Sporicidin Division

525 LOCUST GROVE

SPARTANBURG, SC 29303

(1-800-424-3733)

(Optional additional bullet points for label:)

GENERAL MARKETING CLAIMS

- (All)(Multi-) purpose
- (All)(Multi-) surface
- Cleans and remove(s) (stubborn) (stuck on) (dirt) (messes)
- Also available (in) (as) (spray) (liquid)
- Leaves a clean, fresh (scent) (fragrance)
- Leaves a hospital clean (scent) (fragrance)
- Leaves your (bathroom) (kitchen) fresh and clean
- Ready to use
- For (light touch ups) (quick clean-ups) (in one easy step)
- For household surfaces (all around the house)
- For food processing use
- For residential use
- Great for cleaning around the toilet
- Handles daily clean-ups
- Heavy (light) duty jobs
- Make (your job) (cleaning) (easier) (easy)
- No mixing
- Saves time
- Does not contain phthalates
- Does not contain ortho-phenylphenol [found on Prop 65 List in (California)(CA)]
- Deodorizing activity for up to 6 months (if not removed from surface(s)).
- Provides bacteriostatic activity against odor-causing bacteria for up to 6 months on hard surfaces including (plastics) (latex) (vinyl) (glass) (treated wood) (metal) (glazed porcelain) (glazed tile) (paint) (if not removed from surface(s)).
- An effective cleaner, disinfectant, and active deodorizer for instruments and equipment and on pre-cleaned, hard, non-porous surfaces in (health/hospital treatment and patient rooms) (hospitals) (medical offices) (dental offices) (operating rooms) (schools) (universities) (trauma centers) (crime scenes) (prisons) (ambulances) (hotels/motels) (restaurants) (boats)(planes) (buses) (the home) (fitness centers) (fitness arenas) (airports) (and other industrial/commercial settings) (gym centers) (health facilities)

Proposed Master Label

(spas) (wellness centers) (physical and rehabilitation facilities) (clinics) (transportation service vehicles (Optional -including buses, boats, trains, and planes)) (nail salons) (restoration industries (optional) including water, fire, and mold restoration) (laboratories) (Industrial clean rooms) (controlled/critical environments) (pharmacies) (compounding pharmacies) (veterinary environments) (military facilities)

- Reduces hazards of cross contamination on treated surfaces.
- Disinfecting on non-food contact hard surfaces
- Non-abrasive formula (wipes), Non-staining
- For (institutional,) (industrial,) (household,) (hospital,) (and farm premise) use.
- For (select one or more) - (medical and dental equipment) (beds) (surgical carts) (countertops) (mannequins) (telephones) (cellular/mobile phones) (keyboards) (portable digital music players) (furniture) (wheelchairs) (walkers) (sinks) (floors) (walls) (tables) (light switches) (linen hampers) (shower stalls) (toilet seats) (trash containers) (damp and musty areas) (animal areas) (kitchen counters) (stovetops) (the outside of microwaves) (refrigerators and other similar appliances) (finished hardwood) (cabinets) (diaper pails) (trash cans) (glazed tile) (tubs) (changing tables) (chrome) (bathrooms) (public restrooms) (door knobs) (faucets) (patio furniture) (cribs) (car interiors) (computers) (hand rails) (door frames) (urinals) (desks) (exercise equipment) (yoga mats) (exercise balls) (dining room surfaces)
- Not recommended for use on concrete
- (Optional Brand Name) Disinfectant (Towelettes) is germicidal when used as directed for disinfection.

For residential, institutional, hospital, and farm premise use.

(Label will include organisms either in list format as seen here, or as Table 1 below.)

- **Virucidal****: Avian Influenza A virus (H5N1), Avian Influenza A virus (H9N2), Cytomegalovirus, Herpes simplex virus types 1 and 2 (oral, ocular, and genital), HIV-1 (AIDS Virus). [See (Brand Name) Bulletin No. 303 for special instructions for cleaning and decontamination against HIV-1(AIDS Virus) of surfaces/objects soiled with blood/body fluids], Human Coronavirus, Influenza A virus (H1N1), Influenza A virus (H3N2), Norovirus, Parainfluenza type 3 virus, Polio Type 1 virus, Vaccinia virus.
- **Bactericidal**: Acinetobacter baumannii, Escherichia coli, Methicillin resistant Staphylococcus aureus (MRSA), Mycobacterium bovis (surrogate for mycobacterium tuberculosis (TB)), Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus, Streptococcus pyogenes, Streptococcus salivarius, Vancomycin resistant Enterococcus faecium (VRE).
- **Fungicidal**: Aspergillus brasiliensis, Penicillium variable, Trichophyton mentagrophytes (Athlete's Foot fungus).

Kills/Eliminates: (Optional organisms located in Table 1)

Proposed Master Label

Table 1 – (either this table or above list)

Viruses (5 min contact time)	
Avian Influenza A virus (H5N1)	Strain H5N1-PR8/CDC-RG, CDC#2006719965
Avian Influenza A virus (H9N2)	Turkey/WIS/66
Cytomegalovirus	ATCC VR-538
Herpes simplex virus types 1/F and 2/G (oral, ocular and genital)	Types 1/F and 2/G
HIV-1 (AIDS virus) See (Insert Company Name) Bulletin No. 303	
Human Coronavirus	ATCC VR-740
Influenza A virus (H1N1 Pandemic Flu)	ATCC VR-333
Influenza A virus (H3N2)	ATCC VR-544
Norovirus	Feline Calcivirus, Surrogate for Norovirus (ATCC VR-782)
Parainfluenza type 3 virus	ATCC VR-93
Polio type 1 virus	Brunhilde, ATCC VR-58
Vaccinia virus	VR-119
Bacteria (10 min contact time)	
Acinetobacter baumannii	ATCC 19606
Escherichia coli (E. coli)	ATCC 35150
Methicillin-resistant Staphylococcus aureus (MRSA)	ATCC 33591
Pseudomonas aeruginosa	ATCC 15442
Salmonella choleraesuis	ATCC 10708
Salmonella enterica	ATCC 10708
Staphylococcus aureus	ATCC 6538
Streptococcus pyogenes	ATCC 19615
Streptococcus salivarius	ATCC 7073
Tuberculosis (Mycobacterium Bovis (BCG))	ATCC 35743
Vancomycin resistant Enterococcus faecium (VRE)	ATCC 51559
Fungi (10 min contact time)	
Aspergillus brasiliensis	ATCC 16404
Penicillium variable	ATCC 52262
Trichophyton mentagrophytes (Athlete's Foot fungus)	ATCC 9533

Proposed Master Label

(Brand Name) Bulletin Number 303

(US EPA registration # 8383-3)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS AGAINST HIV-1 (AIDS VIRUS)

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/ BODY FLUIDS in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/ body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

Personal Protection: Disposable latex or vinyl gloves, gowns, facemasks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of Sporicidin Disinfectant Solution (or other brand name).

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1. Disposal of Infectious Material: Blood/body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

(MOLD REMEDIATION MARKETING CLAIMS) (all optional)

- This product inhibits the growth of damage and odor-causing bacteria and fungi on hard, non-porous treated articles and surfaces, such as construction materials.
- This product is used to protect treated articles from mold or mildew.
- This product inhibits odor causing bacteria on hard, non-porous surfaces.
- This product inhibits the growth of mold and mildew and their odors when used as directed.
- This product kills mold and mildew when used as directed.

(SPA/RECREATIONAL ESTABLISHMENT CLAIMS) (all optional)

This product is used to treat the following surfaces in a (Health) (Spa)(Day Spa)

(Recreational) Establishment(s):

- Bathroom and kitchen surfaces, sinks, chairs, stools, mats, trays, massage tables, tables, shower stalls, bathtubs, ice machines, and tub surfaces.
- Glass, metal, stainless steel, glazed ceramic, glazed porcelain, granite, marble, plastic, sealed limestone, sealed slate, sealed stone, sealed terracotta, sealed terrazzo, chrome, and vinyl.
- Enameled surfaces, painted woodwork, Formica®, vinyl and plastic upholstery.
- Foundations, steps, plumbing fixtures, finished baseboards, and window seals.
- Tables/chairs, desks, bed-frames, lifts, washable walls, cabinets, doorknobs, garbage cans, cuspidors, and spittoons.
- Exhaust fans, refrigerated storage and display equipment, coils and drain pans of air conditioning, refrigeration equipment and heat pumps.

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- Large inflatable non-porous plastic and rubber structures: animals, promotional items, moonbounces, slides, obstacle course, play and exercise equipment.
- Hard non-porous surfaces of picnic tables and outdoor furniture
- Telephones and telephone booths
- High chairs
- Drinking fountains
- Shower stalls, shower doors and curtains, bathtubs and glazed tiles, chrome plated intakes, toilet bowls, toilet bowl surfaces, urinals, empty diaper pails, portable and chemical toilets, latrine buckets, glazed porcelain and glazed tiles restroom fixtures.
- Ultrasonic baths, whirlpools, and whirlpool bathtubs

(FARM PREMISES, ANIMAL PENS, POULTRY HOUSES, and VETERINARY CLINIC ESTABLISHMENT CLAIMS) (all optional)

This product is used to treat the following surfaces in (farm premises,) (animal pens,) (poultry houses,) (and) (veterinary clinics):

- Kennels, kennel runs, cages, kennel/cage floors, and conductive flooring
- Hatchers, setters, trays, racks, egg flats, walls, floors, ceilings, chick boxes, egg cases, vans and trash containers

(CLEANING/DISINFECTING MARKETING CLAIMS:) (all optional)

- This product cleans, deodorizes, and controls the growth of damage-causing and odor-causing organisms.
- This product (maximizes) (improves) labor results by effectively controlling odors.
- This product is a ready-to-use product
- This product neutralizes musty odors and tough odors from smoke.
- This product is specially formulated to effectively eliminate offensive odors caused by mold and mildew.
- Eliminates odors caused by bacteria and fungi.
- For use as a mold preventative or remediation treatment in areas where mold can or has been a problem:
 - Commercial and residential buildings.
 - Hospitals, nursing homes.
 - EMS & fire facilities.
 - Day care centers and nurseries.
 - Life care retirement communities, and home healthcare institutions.
 - Restaurants, bars, cafeterias, institutional kitchens, fast food operations and food storage areas.
 - Supermarkets, convenience stores, retail and wholesale establishments, and laundries.
 - Manufacturing facilities.
 - Food establishments, coffee shops, doughnut shops, bagel stores, pizza parlors, liquor stores, and ice cream parlors

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- Police stations, courthouses, correctional facilities, jails, prisons, municipal government buildings, forensic laboratories, animal research and lab facilities.
- Institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels.
- Public restrooms, public facilities, shower rooms, shower stalls, and bathrooms.
- Hotel, motels, and dormitories.
- Kitchens & bathrooms.
- Institutions, schools and colleges, churches, classrooms, community colleges, universities, athletic facilities and locker rooms, exercise rooms, exercise facilities, gyms, and gymnasiums.
- Heath clubs and day spas.
- Recreational facilities, sports arenas, and sports complexes.
- Veterinary clinics, animal life science laboratories, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, and other animal care facilities.
- Boats, ships, and barges, and cruise lines.
- Commercial florist and flower shops.
- Basements, crawl spaces, cellars, bedrooms, attics, and living rooms.
- This product may be used as a cleaner and deodorizer or for water/flood damage clean up, sewage backflow cleaning, and trauma scene cleaning.
- Enameled surfaces, (painted) (finished) woodwork, vinyl and plastic, and upholstery.
- Foundations, stops, plumbing fixtures, finished baseboards and windowsills, washable walls, tables, floors, and cabinets.
- Studs, wallboards, joists, beams, trusses, underlayment, sub-flooring, wood framing, plywood, oriented stand board, ceilings and ceiling tiles.
- Refrigerated storage and display equipment.

(MANDATORY LANGUAGE:)

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

DO NOT DILUTE OR MIX WITH OTHER CHEMICALS

Prior to treatment, check acceptability of fragrance with occupants of the venue.

PRECLEAN surfaces using (Insert Brand Name) Disinfectant Solution to remove soil and filth. Allow to air dry, or wipe dry with paper towel, cloth, mop, or sponge.

TO DISINFECT AND DEODORIZE (electrical panels), (cash registers), (door knobs), (handles), (seats), (dashboards), (and other “high touch” surfaces in and around) (farm equipment), (animal and poultry housing)(housing)(animal barns)(barns)(animal kennels)(kennels)(animal and poultry breeding pens)(breeding pens) (hatcheries),

Proposed Master Label

(trucks), (and vehicles,) thoroughly wipe pre-cleaned surface with (insert brand name) Disinfectant Towelettes and allow surface to remain visibly wet for 10 minutes. Use as many wipes (towelettes) as necessary for the treated area to remain wet for 10 minutes at room temperature (20°C/68°F or above) to kill listed bacteria and viruses. Surface must remain wet for 10 minutes to kill listed fungi.

(optional section) TO KILL, CLEAN AND PREVENT MOLD AND MILDEW: MOLD AND MILDEW CONTROL IN AND ON BUILDING MATERIALS: Before applying this product, visible mold growth must be removed, and the conditions favorable to mold growth must be identified and corrected. Keep children, pets, and livestock away until treated areas have dried following application.

Occupants including pets and livestock must be removed from the containment area prior to treatment. Use procedure stated above. Repeat application if new growth appears.

(optional section) FOR FOOD PROCESSING PLANTS: Follow pre-cleaning and disinfecting instructions outlined above to disinfect hard, non-porous surfaces and materials in food handling areas, including poultry and meat packing facilities, slaughter houses, etc. All surfaces and materials that come in contact with food must be rinsed with potable water prior to use.

(optional section) FOR SPA/RECREATIONAL ESTABLISHMENTS: This product is not a sterilant or high level disinfectant for salon instruments and utensils, and does not replace sterilization processes. For items such as bathrooms and kitchen sinks, chairs, stools, mats, trays, massage tables, tables, shower stalls, bathtubs, ice machines, tub surfaces, and other “high touch” non-porous surfaces, thoroughly wet pre-cleaned surface with (insert brand name) Disinfectant Towelettes and allow surface to remain wet for 10 minutes.

(optional section) FOR HOSPITAL DISINFECTION: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly to 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

(optional section) FARM PREMISE DISINFECTION:

FOR FARM EQUIPMENT, ANIMAL AND POULTRY HOUSING, BARNs, KENNELS, BREEDING PENS, HATCHERIES, TRUCKS AND OTHER VEHICLES: Remove poultry, animals, feed, water, trucks, coops and crates from premises. Remove litter droppings from floors, walls, and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use Sporicidin Disinfectant Towelettes to ensure surface is wet and allow to remain wet for ten minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment

Proposed Master Label

until treatment has been absorbed, set, or dried. Thoroughly wipe treated feed racks, troughs, automatic feeders, fountains, and water appliances with soap or detergent, and rinse with potable water before reuse. Disinfection of equipment: Use Sporicidin Disinfectant Towelettes to cover all surfaces for 10 minutes. Allow to air dry. For Avian Influenza A, the use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, and laboratory benches, facet handles, door knobs, and similar "high touch" surfaces.) For uses in hospital/medical/health facilities, the directions for hospital disinfection must be followed. For all other use sites, general disinfection directions must be followed.

STORAGE AND DISPOSAL(mandatory)

Do not contaminate water, food or feed by storage or disposal.

(Household/Residential):

STORAGE AND DISPOSAL Store at room temperature. Nonrefillable container. Do not reuse or refill this container. Discard empty container in regular trash or offer for recycling if available.

(Commercial/Institutional):

PESTICIDE STORAGE: Store at room temperature.

PESTICIDE DISPOSAL: Dispose of in accordance with local regulations. Do not dispose of in storm drain systems.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(*Optional:* For emergency medical treatment, you may contact the National Pesticide Information Center at 1-800-858-7378 between the hours of 6:30am to 4:30pm (PT) seven days a week. During all other times, call the poison control center at 1-800-222-1222)

(mandatory)

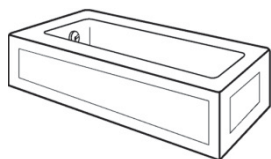
PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID: If in eyes, remove contact lenses. Hold eye open and slowly rinse with water. If irritation persists for more than 5 minutes continue rinsing and consult a physician or poison control center.

Not for personal cleansing.

(Hard non-porous surface pictures such as these:)



Bathtub



Changing Table



Computer



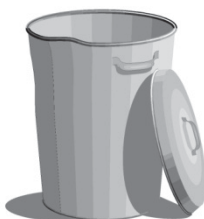
Baby crib



Door Knob



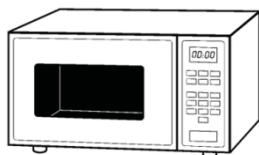
Faucet



Garbage Can



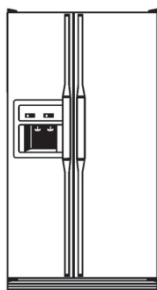
**Kitchen
Countertops**



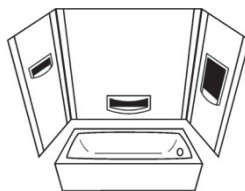
**Outside of
microwaves**



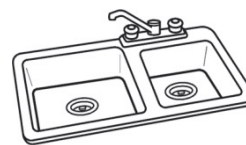
Patio Furniture



**Outside of
Refrigerator**



Tub and Shower walls



Sinks



Stovetop

Proposed Master Label



**Telephone Receivers
and Key Pads**



Toilet