



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 6, 2018

Nate Richardson
President
MonoFoil USA
5540 West 53rd St. Parkway
Anderson, IN 46013

Subject: Label Amendment – Agency initiated label revisions to remove misleading efficacy language and update registration number
Product Name: MonoFoil D
EPA Registration Number: 90856-4
Application Date: September 6, 2018
Decision Number: 546909

Dear Mr. Richardson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Tara Flint via email at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

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Listed uses and use sites can be used partially or in their entirety
<<Front Panel>>

EPA Reg. No.: 90856-4
New Registration: 10/31/2018

Product Name: MonoFoil D

Alternative Trade names: MonoFoil T, PureBond24, MF24, MonoFoil DP, ApplyGuard DP, Apply Guard Daily



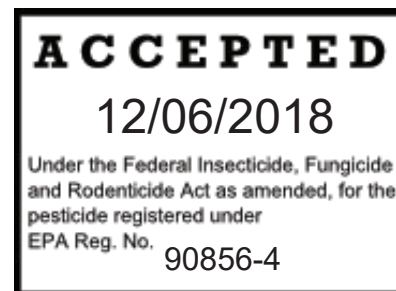
ACTIVE INGREDIENTS:

3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.13%
N-Alkyl Dimethyl Benzyl Ammonium Chloride (60% C14, 30% C16, 5% C18, 5% C12).....	0.51%
INERT INGREDIENTS:.....	99.37%
TOTAL:.....	100%

KEEP OUT OF REACH OF CHILDREN

Read Complete Directions and Precautions on Package – and/or Rear Panels –and/or- Attached Complete Label

- NET WT:
- 1.0 OZ. (28 g)
 - 2.0 OZ. (43 g)
 - 4.0 OZ. (113 g)
 - 6.0 OZ. (170 g)
 - 8.0 OZ. (226 g)
 - 12 OZ. (340 g)
 - 18 OZ. (1 LB. 2 oz.) (510 g)
 - 24 OZ. (1 LB. 8 oz.) (680 g)
 - 32 OZ. (2 LB.) (907 g)
 - 64 OZ. (4 LB.) (1814 g)
 - 80 OZ. (5 LB.) (2268 g)
 - 128 OZ.(8 LB.) (3628 g)
 - 164 OZ.(10 LB. 3oz.) (4649 g)
 - 5 Gallons
 - 20 Gallons
 - 30 Gallons
 - 55 Gallons
 - 250 Gallons
 - 330 Gallons



<<FRONT or BACK PANEL>>

EPA Reg. No.: 90856-4

EPA Est. No.: 092366-IN-001

(See bottom or side) (for Lot/Data code)

NOTE: Bracketed information is denoted as: <<directive>>, {insert as noted}, (optional text), [required qualifier]. The term “this product” used throughout this document may be replaced with the marketed product brand name. To use the term “germ” the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.

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<<BACK PANEL>>

Questions? Comments? (symbol of telephone)

Call: 765-203-2304

For ingredient (and other) information visit [**insert company website**]

Made in U.S.A. ©Apply Guard (year)

Manufactured by: ©Apply Guard, llc., (insert address (-xxxx))

Distributed by: (Distributors name, city, state, zip code)

<<FRONT or BACK PANEL – Optional Text>>

Important facts (about this product):

Learn more about (the importance of good hygiene habits) (and) (the appropriate use of disinfectants) (in good hygiene) (and the many ways that (product name) is promoting good hygiene habits)(for your family and community), (Redefine Clean with (product name)), (Hospital) (Healthcare) grade disinfectant.

(Product name) is both gentle and effective. (Delivering the power of MonoFoil to protect your most important things...your family.) (Powerful enough for the hospital, yet gentle enough for the home)

<<BACK PANEL – Optional text – PROFESSIONAL USE products only>>

Company Logo (©Apply Guard, llc. (graphic) or MonoFoil Clean Redefined (graphic)

(This product) is an important part of (a) (your) comprehensive cleaning program

Make (this product) a part of (an) (your) daily cleaning program

<<FRONT or BACK PANEL CLAIMS- us as bullet point or in paragraph format>>

<<INTRODUCTORY 6-mos. CLAIM>>

Fresh(er), (cleaner) fragrance

New scent

New (and) (improved) (better) fragrance

New look (for) (this product)

New {insert fragrance name} {scent}

New size

New bottle

New spray nozzle

No scent

No smell

<<PACKAGING CLAIMS>>

Bonus Size

Mini

Pocket (size) (pack)

Portable

Purse (size) (pack)

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Travel (size) (pack)

Trial (size) (pack)

Value (size) (pack)

<<MARKETING – PRODUCT PERFORMANCE CLAIMS>>

(Antibacterial Spray) (Antibacterial Action) (Antimicrobial Spray) (Antimicrobial Action)
(Bactericidal) (Bactericidal) (Disinfectant) (Disinfects)
(Daily) (Multi-Action) (Multi-Purpose) (Multi-Room) (Disinfectant) (Antimicrobial)
(Citrus) (Fresh) (Unscented)
(This product) cleans (and disinfects) most (kitchen: non-food contact) (bathroom) (and) (household) surfaces
Anytime (to-go)
Alcohol free
Bleach free (formula) (technology) (disinfection) (disinfectant)
Clean, (fresh) fragrance
Cleaner smelling scent
(Contains) no phosphates
(Does not contain) (No) Sodium Nitrite
(Does not contain) (No) Hydrogen Peroxide
Dual Action (active) (system) (formula)
Disinfects and deodorizes
Disinfects as it cleans
Dye free (formula) (technology) (disinfection) (disinfectant)
Everyday formula
Everyday protection
Effective
For the Holidays
Hospital grade disinfectant
Healthcare grade disinfectant
Lemon
Modern
Non-Abrasive
Non-Abrasive and contains no bleach
No mixing
No hazy residue
No sticky residue
No harsh chemical odor
Refresher Technology
Ready to Use
Suitable for frequent use
MonoFoil Brand
On-the-go
Phosphate free
Quick dry formula
Ready to Use

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Sodium Nitrite free

Stay cleaner longer

The (disinfectant) for Redefining Clean

The (disinfectant) for the New Age of Clean

The (disinfectant) for the new millennium

The Power of MonoFoil

To-Go (anytime)

Versatile Formula

<<USAGE CLAIMS>>

Apply (this product) on surfaces that you and your (family) (patients) come in contact with every day (including): {insert use surfaces}

Controls (kills) (99.9%) (growth of) bacteria, (on) (in) {insert use surfaces} {Insert use site}

Disinfects hard non-porous non-food contact surfaces (in {insert use sites}

Disinfects soft surfaces (in {insert use sites}

For Hospital Use (graphics)

(For use in) hospitals (and homes) (as a) (disinfectant)

For use in institutional (and industrial) (facilities)

For use on hard, non-porous surfaces located in: {insert use sites}

Great for spot disinfection – target performance

Multi surface hard non-porous disinfectant for your surfaces

Multi-purpose Disinfectant (Antibacterial) cleaner

(This product) (disinfects) the following surfaces {insert use surface}

(This product) (disinfects) (in) (the following area) {insert use sites}

(This product) is approved for use in {insert use sites}

(This product) disinfects the surfaces of a wide variety of substrates

Treats, does not cover up

Use (This product) on hard to reach areas (like nooks and crannies)

Use (This product) (in) (under) (around) (on) {insert use site}

Use (This product) (on) {insert use surfaces}

<<NON-PUBLIC HEALTH CLAIMS>>

(Reduces) (Controls) the growth of odor causing bacteria (on (kitchen non-food contact) (bathroom) (and) (household, commercial) surfaces).

(Reduces) (Controls) the growth of odor causing bacteria (on (kitchen non-food contact) (bathroom) (and) (household, commercial) surfaces) for (14, 30 days), (up to 6, 12 months).

<<DEODORIZING CLAIMS>>

Controls (the toughest) (tough) (kitchen) (bathroom) odors caused by (bacteria*) (mold) (mildew)

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Controls (the toughest) (tough) pet odors caused by (bacteria*)

Controls odors caused by mold and mildew

(This product) Deodorizes by killing (many) (bacteria*) that cause odors.

Ordinary non-germicidal spray can't do this.

Deodorizes with new fresh, (pleasant) (no) fragrance

Does not just mask odors, eliminates them at the source

Eliminates (removes) (the toughest) (tough) odors (caused by) (bacteria*)

Gets rid of (the toughest) (tough) odors by killing the (bacteria*) (that cause them) (at the source)

Gets to the heart of (the toughest) (tough) odors

Helps eliminate the build-up of odors by killing odors by killing odor-causing bacteria* (on hard non-porous food contact surfaces)

Helps eliminate the build-up of odors by killing odors by killing odor-causing bacteria* (on soft surfaces)

Odor fighter

De-Stinkify

Refresher technology

Eliminates the growth of odor causing bacteria between cleanings.

Perfect for eliminating your toughest odors at their source

Reduces (controls) (odor-causing bacteria) (on surfaces)

(This product) Eliminates (the toughest) (tough) odors at their source

(This product) eliminates odors at their source caused by (bacteria*)

(This product) (is specially formulated to) eliminate odors (from) {insert use sites} {insert use surfaces}

To eliminate odors use (this product) around {insert use sites} {insert use surfaces}

Use (This product) every day throughout your (house) (home) (office) (school) (area) (workplace) to eliminate odors caused by bacteria

<<DISINFECTING CLAIMS>>

An effective disinfectant, non-food contact surfaces for use in the kitchen, bathroom, bedroom and other household areas.

(Controls) (Kills) odor-causing (bacteria*)

Disinfection Control (Formula)

Disinfects and deodorizes by killing common (household) (hospital) (bacteria*) and controlling their odors.

Dries quickly

Effective against (bacteria*): {insert 'A -B - C' organisms}

Odor (killer) (destroyer) (eliminator)

Gives treated surfaces effective protection against many bacteria

Hard surface disinfectant and odor eliminator

Helps eliminate odor-causing bacteria

Eliminates the spread of bacteria on treated surfaces

Eliminates household odors and bacterial growth on treated surfaces

Kills (Destroys) (Eliminates) 99.9% (of) (bacteria*)

Kills (Eliminates) 99.9% of {insert 'A-B-C' organism}

Kills (disinfects) against {insert 'A-B-C' organism}

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Kills (bacteria*) all over your (home) (office) {insert site use}

Kills (bacteria*) help your house (home) (office) smell cleaner

Kills (bacteria*) protect your house (home) (office)

Kills (bacteria*) (whenever) (wherever) you need (want) it.

Kills (household) (hospital) (healthcare) (kitchen non-food contact) (office) (bathroom) (bacteria*)

Kills *Pseudomonas Aeruginosa*

Kills *Salmonella Enterica*

Kills *Staphylococcus Aureus*

Kills (the following) (household) (hospital) (healthcare) (kitchen(non-food contact)) (bathroom)

(office) germs**. {insert 'A-B-C' organisms} (in 10 minutes)

Kills (bacteria*)

Leaves surfaces (disinfected) (cleaner)

Hard Surface (disinfectant) (cleaner)

On environmental surfaces, (this product) kills the following bacteria, {insert 'A-B-C' organisms}

Provides effective protection against many household germs

Surface Disinfectant

(This product) cleans and disinfects

(This product) (controls) (kills) the (bacteria*) that cause unpleasant odors (at the source)

(This product) (also) eliminates odor causing (bacteria*) (at their source) (to leave your home smelling) (fresh) (pleasant) (clean)

(This product) (MonoFoil Brand Products) (helps) (aids) in the reduction of cross contamination of (germs) (antibiotic resistant bacteria) (on hard, non-porous surfaces)

Kills household bacterial growth* on treated surfaces

Kills active bacteria growth* on treated surfaces

(This product) kills {insert 'A-B-C' organisms} (in 10 minutes)

Provides effective protection against many household bacteria*.

Kills many bacteria*

(This product) kills the (bacteria*) that cause (bad) odors

You can also use (this product) in places that are difficult to (disinfect) (sanitize) (reach) such as nooks and crannies.

Your family comes in contact with germs everyday (both in the home and in public (places) (this product) kills 99.9% of bacteria commonly touched (environmental) surfaces (in your home) (in public places) (in the hospital).

NOTE TO REVIEWER- *If any of the above claims are used on the label, they will be footnoted on the back label as follows:*

**Staphylococcus aureus (Staph), Salmonella Enterica (Salmonella), Pseudomonas aeruginosa*

10-Minute DISINFECTION CLAIM

(FRONT/SIDE PANEL)

Kills (destroys) (eliminates) 99.9% of (bacteria) in 10 minutes

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Kills (destroys) (eliminates) 99.9% of (bacteria) in 10 minutes (on) (hard) (environmental surfaces)

(BACK PANEL QUALIFIER)

Kills (destroys) (eliminates) 99.9% of (Pseudomonas aeruginosa) (Salmonella Enterica) (Staphylococcus aureus) in 10 minutes

Kills (destroys) (eliminates) 99.9% of (the following) (household) (hospital) (kitchen) bacteria* Pseudomonas aeruginosa) (Salmonella Enterica) (Staphylococcus aureus) in 10 minutes

<<USE DIRECTIONS>>

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using the product. Do not use on food contact surfaces. Do not use on food contact utensils, glasses or dishes.

Hard Surface: Spray Shake well. Shake well. (This product) comes ready to use. Spray directly onto surface, spray entire surface area 4"-6" from hard, non-porous surface until completely wet; surface must remain wet for 10 minutes and then allow to air dry.

(To Disinfect) (For 10 minute disinfection): Let stand for ten (10) minutes then allow to air dry.

To Deodorize:

Spray on surfaces as needed.

To Control (the Growth of) bacteria (and their Odors) (on Surfaces): Pre-clean of debris. Spray surface with an even coat of (This product). Allow surface(s) to air dry. Repeat applications in weekly intervals or when mold and mildew growth appears.

<<ADVISORY STATEMENT>>

Does not harm polished wood, painted surfaces, leather, textiles, or acrylic plastics
For other surfaces, spot test in an inconspicuous area.

<<Animal Care Facilities>>

Veterinary Practice/Kennels/Poultry houses/Animal Care Facilities: For disinfecting hard, non-porous surfaces including equipment, utensils, cages, kennels, hatchers, setters, trays, racks, egg flats, walls, floors, ceilings, chick boxes, egg cases, vans, trash containers and teat and milking equipment etc. Remove all animals and feeds from the premises, crates, cages, and enclosures. Remove all litter, droppings, and manure from floors walls, and surfaces occupied or traversed by animals. Empty all troughs, racks and other feeding/watering appliances. Thoroughly clean surfaces with (This product). Do not house animals or employ equipment until treatment has been absorbed, set, and dried.

<<MICROORGANISMS- must be identified by genus & species. Abbreviations may be include but must appear in (parens).>>

<<Hard non-porous surfaces>>

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<<A. 10-min Disinfection against Bacteria >>

Pseudomonas aeruginosa (Pseudomonas)	(ATCC 15442)
Salmonella (choleraesuis) Enterica (Salmonella)	(ATCC 10708)
Staphylococcus aureus (Staphylococcus)	(ATCC 6538)

Symbol Designation – used on product labels:

Single asterisk (*) bacteria/fungi* used for identifying disinfection against specific bacteria or fungi

<<SURFACES – Graphic – depicting surface >>

Hard Non-porous: Not to be used on Food Contact Surfaces

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Bathroom surfaces	Examination tables	Mirror
Bathtub (Tub) (tile)	Fixtures	No wax floors
Bed Frame	Floors	non-wood baby furniture
Bed Springs	Faucets	(non-wood) Cabinets
Bidet	garbage (cans) (pails) (bins)	Non-wood) chairs
Brackets	Glass.	(non-wood) crib
Brass	Glass-topped Furniture	(non-wood) Highchair (non-food)
Cat litter boxes	Glazed ceramic tile	(non-wood) (Kitchen)
Chrome"	Glazed Porcelain	Counter (Countertop)
Clean-up carts	Hard (non-porous) surfaces	(Non-wood) Outdoor
Copper	(Household) tools	(patio) Furniture
Crystal	Laminate (surfaces)	Parquet
Cupidors	Lamps	Patient Chairs
Desk	Light switches	Pens
(Diaper) changing	Linoleum	Plastic
(Counters) (Tables)	Litter boxes	Plastic (baby) (Children)Toys'
Diaper Pails	Marble (Cultured)	Plastic Laundry Basket (Hamper)
Dish Pails	Marble (Synthetic)	Plastic mattress covers
Dish Racks	Marlite	Plexiglas®
Door Knob (handle)	Metal"	Porcelain (tile)
Drains'	Metal Blinds	Portable Toilet
Dressing carts	Microwave (oven) exteriors	Recycling bins
Drinking Fountains		Refrigerators (exteriors)
Enamel		
Remote controls	(Resilient)(ceramic)Floor	Salad Bar Sneeze Guards
Sealed Granite	Shower (Stall) (Area) (doors)	Shower (curtain) (plastic)(liner)
Sinks (basin)	Sports equipment	Stainless Steel"
Stretchers	Table (tabletops)	Telephones
Textiles	Tin	Toilet (Seats) (areas)
Toweletts	Tile	Urinals
Under sinks	Vinyl	Non-Wovens
Washable Walls	Wheelchairs	Whirlpool interiors/exterior
Windows (windowsills)		

®Plexiglas is a registered trademark of the Atofina Corporation
 Follow directions for Toys under Directions for Use.

<<HOUSEHOLD USE SITES – Graphic – depicting surface>>

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Attic	Automobile	Litter boxes	Living Room
Basement	Bathroom	Lockers	Mobile Home
Bedroom	Boat'	Mud Room	Nursery
Cabins	Camper	Pet areas	Playroom
Car	Closets	Public eating places	Public facility
Campers	Den	Public seating places	Public places
(damp) Storage Area/Room	Study	(Public) restrooms	Studios
Dining Room	Dorm	Sun rooms	Supermarket (grocery store)
Exterior	Family Room	Tool Shed	Vacation home
Garage	Home / House	Vehicles	
(Home) Workshop	Kitchen		
Laundry Room			

<<PROFESSIONAL USE SITES – Graphic – depicting surface>>

Airplane	Auto	(Institutional) kitchen	(Institutional) Laundromat
Ambulance	Blood Bank	(Institutional) Restroom	Kennel
Boat	Bowling Alley	Kitchen	Laboratory
Business	Cafeteria	Manufacturing Plant	(Medical) Clinic
Campground (facility)	Clinics	Military Installation	Nursery
College	Commercial Building	Nursing Home	Office (Buildings)
Convenience stores	Day Care Centers	Patient Rooms	Pharmacy
Dental Office	Doctors Office	Physician's Office	Playground (facility)
Factory	Food service	Public places	(Public) restrooms
Gymnasium (gym)	Health Care Facility	Public telephones (booth)	Recreational Center
Hatchery	Health Club	Restaurant	School
Hospital	Hotel / Motel	School Bus	Shelter
Infirmiry	Industrial Building	Teat Machines	Sick rooms
Institutional Bathroom	(Institutional)	Toll Booth	Train Interior
		Veterinary (office) (clinic)	

<<PRECAUTIONARY /FIRST AID/ STORAGE – DISPOSAL INSTRUCTIONS>>

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New Registration: 10/31/2018**

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

Caution: Causes moderate eye irritation. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contact with eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for about 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none"> • Take off contaminated clothing • Rinse skin immediately with plenty of water for 15-20 minutes • Call a Poison Control Center or doctor for treatment advice.
CONTACT NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxx for emergency medical treatment information. Questions? Comments or in case of an emergency, call toll free (local phone number) (toll free number).</p>	

<<Storage and Disposal language >>

STORAGE AND DISPOSAL: Store in original container in areas inaccessible to small children. Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

Optional graphics like these or consistent with approved areas, may be placed anywhere on label/container or collateral labeling.



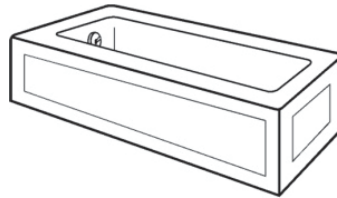
>>, {insert as noted}, (optional text), [required qualifier]. The term "this product" marketed product brand name. To use the term "germ" the product must be on the product label must identify the specific bacteria, virus, fungus & mold.

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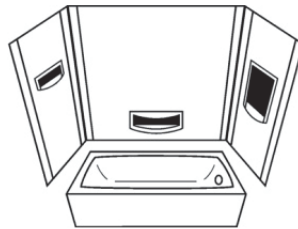
Telephone Receivers and Key Pads



Bathtub



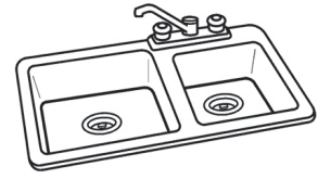
Changing Table



Tub and Shower walls



Computer



Sinks

NOTE: Bracketed information is denoted as: <<directive>>, {insert as noted}, (optional text), [required qualifier]. The term "this product" used throughout this document may be replaced with the marketed product brand name. To use the term "germ" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.