

70627-24

4-10-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 10 2000

S.C. Johnson Commercial Markets, Inc.
8310 16th Street, MS 675
Sturtevant, WI 53177-0902

Subject: Virex II/256
EPA Registration No. 70627-24
Amendment Date: 10/5/99
EPA Receive Date: 11/07/99

Attention: Ms. Lisa Amadio

The amendment referenced above, submitted in connection with registration under FIFRA, as amended, to add use dilution labeling is acceptable provided you address the following comments before you release this product for shipment.

Product Chemistry

The Confidential Statements of Formulas for alternate formulations #21786, #21794, #21795, #21796, #21798, #21801, #21802, and #21815 dated 9/28/99 are acceptable, in compliance with PR Notice 91-2, and in agreement with the label. The fragrances, PA 51864, and TCC 79048, are cleared for use in pesticide formulations.

Acute Toxicology

The proposal for a regulatory distinction between lethality due to corrosive effects and lethality due to systemic toxicity is unacceptable. The cited acute inhalation study represents controlled conditions far in excess of those normally experienced by product users. Similarly, the cited acute dermal toxicity study on this product employed excessive conditions such that the study was halted due to corrosion. However, Agency policy does not recognize the distinction between "systemic" and "corrosion" effects. Acute dermal and acute inhalation studies are conducted at high concentrations on purpose to test the lethality and to get an indication of what effects might result from emergency exposure incidents.

Your recommendation for Category III for acute inhalation toxicity based on an LC₅₀ adjustment for dilution (2:1 aqueous only) is unacceptable. Also, your proposal to use the acute

CONCURRENCES

SYMBOL	75702						
SURNAME	Campbell						
DATE	4/10/00						

oral LC₅₀ to determine the acute inhalation LC₅₀ is unacceptable.

Based on the 2/17/00 meeting between the Agency and SC Johnson Commercial Market representatives, you demonstrated that this product's concentrate will never be sprayed. You also indicated that the product will typically be poured or delivered into a closed system; never to be applied at full-strength, only as 1:256 dilution. With that in mind, the Agency has determined that acute exposure concerns for routine, non-emergency conditions can be considered minimal when the product concentrate is merely poured into a closed delivery system. However, in emergency incidents with the closed system, the label must have appropriate protective equipment immediately available. Therefore, the Agency will allow the following precautionary statements to address the inhalation toxicity for this product label.

Concentrate may be fatal if inhaled. Do not breathe spray mist. The use of a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)* is required except when the product is used in a closed delivery system, in which case, it must be provided and immediately available for use in an emergency, such as a spill or equipment break-down.

You will need to revise this product's Precautionary and First Aid Statements according to the Agency letter dated 9/3/99 with the exception of the above acute inhalation guidance. The revisions are outlined below in bold font.

Concentrate "Precautionary Statements" Revisions:

Corrosive. **Concentrate** causes irreversible eye damage and skin burns. **Concentrate may be fatal if absorbed through the skin.** Do not get in eyes, on skin, or on clothing. Wear chemical splash-proof goggles or face shield, rubber gloves, **protective clothing**, and protective footwear. **Concentrate may be fatal if inhaled.** Do not breathe spray mist. **The use of a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)* is required except when the product is used in a closed delivery system, in which case, it must be provided and immediately available for use in an emergency, such as a spill or equipment break-down. (See PR Notice 98-9 for accurate respirator guidance).** Concentrate is harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

Use dilution Revisions:

Precautionary Statements:

After product is diluted in accordance with the Directions For Use, causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, clothing. Harmful if inhaled. Avoid breathing spray mist. Protective eyewear, clothing, gloves, and respirator are not required. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Statements of Practical Treatment: These statements should be separated from the

Concentrate's First Aid statements.

If the diluted product gets: In Eyes, flush eyes with plenty of water. Call a physician, if irritation persists. If On Skin, wash with plenty of soap and water. Get medical attention.

Efficacy

- 1. The data submitted supports efficacy claims against the following organisms:
 - A. *Enterobacter liquefaciens* (ATCC 14460)
 - B. *Proteus mirabilis* (ATCC 9240)

- 2. The listing of the commonly used alternate names for an organism, specifically *Streptococcus faecalis* (ATCC 14460), *Serratia liquefaciens* (ATCC 14460), and *Pseudomonas cepacia* (ATCC 25416), is not acceptable. According to Subdivision H, section 101-1 p.9, "Bacterial, fungal, and viral nomenclature used on product labels should appear in the last edition of the American Type Culture Collection (ATCC) catalogs." It is the responsibility of the manufacturers and consumers of these antimicrobial products to keep up to date with the current scientific nomenclature. However, you may list the alternate name(s) for a micro-organism after the current designation; for example *Enterococcus faecalis* (formerly *Streptococcus faecalis* (ATCC 19433) and *Serratia liquefaciens* (ATCC 14460). They should not be listed separately.

Label Recommendations

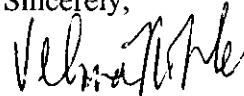
- 1. Page 2: Under Hospitals/Health Care Facilities, delete "[and] [hospital] medical equipment [& devices,]" and state "medical equipment surfaces".
- 2. Page 2: Under General Uses and Hospitals/Health Care Facilities, delete "whirlpools" from your list of sites. You will need to develop specific use directions on how to clean.
- 3. Pages 2-3: Under General Uses, Hospitals/Health Care Facilities, and Food Service, the phrase, "Do not use on glasses, dishes, and utensils" needs to be added as the last sentence in the second paragraph.
- 4. Pages 2-3: Under General Uses, Hospitals/Health Care Facilities, and Food Service, the phrase, "a variety of" needs to be replaced with "the following" from the first sentence in the second paragraph.
- 5. Pages 2-3: Under each heading in second paragraph, delete "typically" from the phrase "typically associated with."
- 6. Page 3: Under Food Service, revise the first phrase in the first paragraph to state either "As a cleaner, VIREX II/256 removes dirt ..." or "VIREX II/256 cleans by removing dirt,..."

- 7. Page 4: The heading, "For Use as a Cleaner," needs to state "For Use as a Cleaner *and/or* Deodorizer."
- 8. Page 4: Under One-Step Cleaner/Disinfectant, you will need to add an additional note for food processing plants/federally inspected meat and poultry establishments:

"Before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water."
- 9. Page 5: You need to revise the heading, "To Kill Mold and Mildew" by stating "To Kill Mold and Mildew in 5% soil load". The distinction between killing and controlling mold and mildew is determined by the soil load.
- 10. Page 6: Under Treatment of Animal Housing Facilities, the seventh step should be revised by stating, "*To disinfect* feed racks, troughs, automatic feeders, fountains, and watering appliances scrub with use solution, let stand for ten (10) minutes. *Then, thoroughly scrub all treated surfaces with soap or detergent and rinse with potable water.*" (See DSS/TSS 18, step 9)
- 11. Page 6: Under Claims, the first statement
- 12. Page 7: Under Viruses list, You will need to separate HIV-1 (AIDS virus) (HTLV-III_B) from the other viruses because this product is efficacious against this organism in one minute instead of ten minutes.

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label to the Agency before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510C)

Enclosure: Acute Toxicology Data Evaluation

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(Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.)



VIREX™ II/ 256

One-Step Disinfectant Cleaner And Deodorant

*Bactericidal • *Virucidal • Fungicidal • Mildewcidal • (Mildewstatic) • Deodorizer (Odor Counteractant) (Odor Neutralizer) • Non-Dulling To Floors (Floor Finishes)*



For (Hospital,) (Foodservice,) (Commercial,) Industrial & Institutional Use (Only)
(Suitable) For Use in Meat and Poultry Plants
Keep From Freezing

ACTIVE INGREDIENTS:	
Didecyl dimethyl ammonium chloride.....	8.704%
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride.....	8.190%
INERT INGREDIENTS:	83.106%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

ANGER: PELIGRO:

See additional precautionary statements on back (side) (left) (right) (panel) (of) label (below).

See reference sheet (enclosed in each case) for a complete list of pathogenic organisms eliminated by VIREX™II/ 256 (this product).

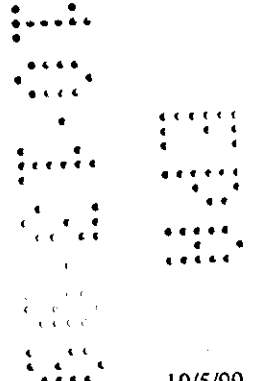
Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 10 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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(Product of USA)



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(MARKETING CLAIMS): (Note to EPA - This text will only appear on the appropriate container.)

ACCUMIX™ CONTAINERS (32 oz. container) - ACCUMIX™. (Remove [Loosen] cap). Squeeze. (Squeeze bottle.) Measure. (Measure amount). Pour. (Pour contents). (Designed) For use with 5 gallon Buddy Jugs™ (the BIG BUDDY™ [ACCUTAINER™] System). VIREX™ II/ 256 can also be diluted into pre-cleaned and properly labeled 5-gallon BUDDY JUG™ (ACCUTAINERS™) (Dispensing Containers) for dispensing as needed.

SOLUTIONS CENTER™ (64 oz. containers) - For use with (JOHNSON™) (PRISM™) (DRACKETT™) (SOLUTIONS CENTER™) Brand Dispensing Equipment. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. Disinfectant Cleaning With The Convenience Of (SOLUTIONS CENTER™). (SOLUTIONS CENTER™) (This) packaging offers) Reduced Exposure To Concentrate Due To Closed Transfer System. Solutions To Go!

J-FILL™ DISPENSING SYSTEMS (84.5 oz. containers) - For use with (JOHNSON™) (PRISM™) (DRACKETT™) (J-FILL™) Brand Dispensing Equipment. Eliminates Mixing. The Accurate Solution To Cleaner Dilution. Disinfectant Cleaning With The Convenience Of J-FILL™. J-FILL™ (This) packaging offers) Reduced Exposure To Concentrate Due To Closed Transfer System. Solutions To Go!

ACCUPACK™ CONTAINERS (Pre-measured packets) - Pre-Measured [Tear-Open] Packets.

(FEATURES, CLAIMS & USES:)

(General Uses)

VIREX™ II/ 256 is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (and controlling mold and mildew on) (of) a variety of hard, non-porous environmental surfaces. It cleans quickly by removing dirt, grime, mold, mildew, body oils and other common soils found in hospitals, nursing homes, schools and colleges, (day care centers), (medical) offices, funeral homes, veterinary clinics, pet shops, (equine farms), animal life science laboratories, hotels, motels, public areas and restrooms, foodservice establishments (restaurants) and federally inspected meat and poultry establishments (food [processing] plants).

It is designed for use on (Use daily on) (a variety of) hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces typically associated with floors, walls, ceilings, tables, chairs, countertops, telephones, fixtures, whirlpools, glazed tile, toilets, urinals, bowl brushes, (bowl mops), sinks, shower rooms and locker rooms areas - any washable (food and non-food contact) surface where disinfection is required. VIREX™ II/ 256's non-dulling formula eliminates the time and labor normally required for rinsing. A potable water rinse is required for food contact surfaces.

(Hospitals/Health Care Facilities:)

VIREX™ II/ 256 is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (and controlling mold and mildew on) (of) a variety of hard, non-porous environmental surfaces. VIREX™ II/ 256 cleans quickly by removing dirt, grime, mold, mildew, food residue, body oils, dead skin, blood and other organic matter commonly found in hospitals (and) (in health care facilities) (on medical surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

VIREX™ II/ 256 cleans, disinfects and deodorizes (hard, non-porous environmental hospital (medical) surfaces) in one step (with no rinsing required). Its non-abrasive formula is designed for use on (Use daily on) (a variety of hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, laminated surfaces and baked enamel surfaces typically associated with floors, walls, ceilings, tables, chairs, countertops, telephones, fixtures, whirlpools, glazed tile, toilets, urinals, bowl brushes, (bowl mops), sinks found in (health care facilities [hospitals],) patient rooms, operating rooms, ICU areas, shower rooms, and locker rooms. (It can also be used to pre-clean and disinfect hospital items: wheelchairs, [hospital] [patient] bed rails and linings, wash basins, bed pans, [and] [hospital] medical equipment [& devices,]) - any washable (food and non-food contact) surface (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces.

ACCEPTED
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(Food Service:)

VIREX™ II/ 256 removes dirt, grime and food soils in food preparation and processing areas. Its non-abrasive formula will not harm (scratch) surfaces. It cleans, disinfects and eliminates odors leaving surfaces smelling clean and fresh. Use where odors are a problem.

Its non-abrasive formula is designed for use on (Use daily on) a variety of hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, aluminum, stainless steel, brass, copper, laminated surfaces and baked enamel surfaces (typically associated with floors, walls, ceilings, tables, chairs, countertops, fixtures, glazed tile, toilets, (toilet bowls), urinals, sinks found in food establishments, (restaurants), (commercial kitchens) & restrooms. A potable water rinse is required for food contact surfaces.

(Animal Housing Facilities:)

VIREX™ II/ 256 cleans by removing dirt, grime, mold, mildew, blood, urine, fecal matter and other common soils found in animal housing facilities, livestock, swine or poultry facilities, grooming facilities, farms, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.

VIREX™ II/ 256 cleans, disinfects and deodorizes (hard, non-porous environmental surfaces) in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) hard, non-porous surfaces: plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces (typically associated with floors, walls, countertops, cages, kennels, animal equipment) found in (barns, pens and stalls) animal housing facilities.

(Public Restrooms:)

VIREX™ II/ 256 is a one-step disinfectant cleaner and deodorant (odor-counteractant) (odor-neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (and controlling mold and mildew) on (of) a variety of hard, non-porous environmental surfaces.

VIREX™ II/ 256 cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms and mold & mildew. Its non-abrasive formula is designed for use on (restroom surfaces:) glazed ceramic (restroom) tile, glazed porcelain, chrome, stainless steel and plastic surfaces typically associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

(Non-Acid Bowl [& Bathroom] Disinfectant Cleaner:)

VIREX™ II/ 256 is a (concentrated) non-acid (bowl and) bathroom cleaner which cleans, disinfects and deodorizes in one easy step. It cleans, disinfects and deodorizes toilet bowls, urinals, bowl brushes (bowl mops), rims, sinks, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel, and all hard non-porous, washable surfaces found in the bathroom (restroom) (in the presence of organic soil).

VIREX™ II/ 256 eliminates odors leaving bathrooms (restrooms) smelling clean and fresh. Use where odors are a problem. It cleans, disinfects and deodorizes surfaces by killing many odor-causing microorganisms and mold & mildew. Its non-abrasive formula is designed for use (Use it daily) on ([hard, non-porous environmental] restroom surfaces:) glazed ceramic (restroom) tile, glazed porcelain, chrome, stainless steel and plastic surfaces typically associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

(For Refilling Concentrate From Large Containers Into Smaller Containers:)

VIREX™ II/ 256 may be used to fill and refill clean, properly labeled containers for dilution elsewhere within your facility. Make sure the small container has been cleaned, dried and properly labeled. Also make sure other items (funnels or hand pumps) are properly cleaned and dried. To refill, simply pour (or pump product) from the larger container directly into the smaller one being careful not to spill any product. Keep both containers sealed when not in use. When ready for use, mix product according to the directions below.

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[NOTE TO AGENCY: All unbolded italicized phrases, which appear in the Directions for Use, are explanatory and are not to be considered label text. They are included for clarity to the agency only.]

DIRECTIONS FOR USE:

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

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 blood stream 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.

VIREX™ II/ 256 can be applied by mop, sponge, cloth, paper towel, (hand pump) trigger sprayer, tank sprayer, (mechanical spray device,) auto-scrubber or (broadcast) foam gun (device). Change cloth, sponges or towels frequently to avoid redeposition of soil. For disinfection, all surfaces must remain wet for 10 minutes.

To Prepare Use Solution:

Add the product at ½ oz. per gallon of water (4 mL/L) (1:256).

(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on that container size.)

ACCUMIX™ CONTAINERS (32 oz. container) - Add the product at 1/2 oz. per gallon of water (4mL/L) (1:256).

SOLUTIONS CENTER™ (64 oz. containers) - Remove cap and insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, squeeze the handle or press the button to dispense a 1:256 solution into a bucket, bottle, scrubber or other container.

J-FILL™ DISPENSING SYSTEMS (84.5 oz. containers) - Remove cap and insert cartridge into dispenser. Note: See dispenser instructions for proper cartridge placement. Once cartridge is in place, squeeze the handle or press the button to dispense a 1:256 solution into a bucket, bottle, scrubber or other container.

ACCUPACK™ CONTAINERS (Pre-measured packets) - (Simply) open and pour contents into xx gallons of water (for a 1:256 dilution). Keep packets in box until ready to use. (Pour contents of packet into xx gallons of water for a 1:256 dilution.)

(Special Instructions for ACCUPACK CONTAINERS.)

For Use as a Non-Acid Bowl Cleaner/Disinfectant in Toilet Bowls from Concentrate:

1. Pre-clean heavily soiled areas.
2. Pour packet contents into toilet bowl.
3. Swab entire surface area especially under the rim.
4. Allow entire surface to remain wet for ten (10) minutes.
5. Flush toilet and rinse swab applicator thoroughly.

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For Use as a One-Step Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution to hard, non-porous environmental surfaces.
3. To disinfect, all surfaces must remain wet for ten (10) minutes.
4. Wipe surfaces (and let air dry).

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Note - Rinsing is not necessary unless floors are to be coated with finish or restorer. All food contact surfaces such as appliances and kitchen countertops must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

For Use as a Cleaner:

Apply Use Solution to surfaces. Wipe surfaces (and let air dry).

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To Kill Mold and Mildew:

Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous environmental surfaces. Allow surfaces to remain wet for ten (10) minutes. Wipe surfaces (and let air dry).

To Control Mold and Mildew:

Apply Use Solution to hard, non-porous environmental surfaces. Allow to air dry. Repeat application weekly or when growth reappears.

To Kill Fungi:

Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous environmental surfaces. Allow surface to remain wet for ten (10) minutes. Wipe surfaces (and let air dry).

For Use To Clean and Disinfect Barber and Beauty/Manicure Instruments and Tools:

1. Pre-clean heavily soiled items.
2. Completely immerse pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other non-porous instruments in the Use Solution so that surfaces remain wet for ten (10) minutes.
3. Rinse surfaces thoroughly and let air dry before reuse.
4. Change solution daily or when visibly dirty.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and other metal instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

For Use as a Non-Acid Bowl Cleaner/Disinfectant in Toilet Bowls from Concentrate:

1. Pre-clean heavily soiled areas.
2. Add 3/8 oz. into toilet bowl for a 1:256 dilution.
3. Swab entire surface area especially under the rim.
4. Allow entire surface to remain wet for ten (10) minutes.
5. Flush toilet and rinse swab applicator thoroughly.

For Use as a Non-Acid Bowl Cleaner/Disinfectant in Toilet Bowls [and Urinals] from Use-Dilution:

1. Pre-clean heavily soiled areas.
2. Empty toilet bowls by forcing water through the trap. Apply Use Solution to exposed surfaces in toilet bowls and urinals.
3. Swab entire surface area especially under the rim.
4. Allow entire surface to remain wet for ten (10) minutes.
5. Flush toilet or urinal and rinse swab applicator thoroughly.

For Use To Clean and Disinfect Shower Rooms, Locker Rooms and Other Large, Open Areas with Floor Drains:

1. Pre-clean heavily soiled areas.
2. Apply Use Solution to floors, walls and ceilings making sure not to over spray. To disinfect, all surfaces must remain wet for ten (10) minutes.
Special instructions for foam guns: Pour concentrate into foam gun bottle and attach bottle to spray nozzle and ensure gun is attached to hose. Note: See foam gun instructions for more information. Make sure setting is set for a 1:256 dilution. Once in place, squeeze the handle to dispense foam solution. To disinfect, all surfaces must remain wet for ten (10) minutes.
3. Scrub using a deck brush or other coarse material as necessary.
4. Rinse surfaces thoroughly and let air dry.

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For Use For Treatment of Animal Housing Facilities:

1. Remove all animals and feeds from areas being treated.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
3. Empty or cover all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap and detergent and rinse with water.
5. Apply fresh Use Solution to floors, walls, cages and other washable hard, non-porous environmental surfaces. For smaller surfaces, use a trigger spray bottle to spray all surfaces with solution until wet. To disinfect, all surfaces must remain wet for ten minutes.
6. Do not house animals or re-employ equipment until product has dried.
7. To clean and disinfect feed racks, troughs, automatic feeders, fountains and watering appliances scrub with use-solution, let stand ten (10) minutes and rinse with potable water before reuse.

***VIREX™ II/ 256 kills HIV-1 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 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 Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

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

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of VIREX™ II/ 256.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1 and for 10 minutes to kill all other organisms cited on the label.

Disposal of Infectious Material: Blood and other body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

(CLAIMS:)

When used as directed at a 1:256 dilution (1/2 oz. per gallon of water) (4mL/L), VIREX™ II/ 256 contains 660 ppm of active quaternary germicide making it highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms.

Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), in the presence of 400 ppm hard water, 5% serum load and 10 minutes contact time, VIREX™ II/ 256 kills the following:

Viruses (*Virucidal Activity) – kills on hard non-porous inanimate surfaces:

Adenovirus Type 2, (VR-2)

Fungi/Yeast (Fungicidal and Yeast Activity) – kills on hard non-porous inanimate surfaces:

Fungi:

Aspergillus niger, (ATCC 6275)

Trichophyton mentagrophytes (athlete's foot fungus), (ATCC 9533)

Yeast:

Candida albicans, (ATCC 10231)

Mold/Mildew (Mildewcidal Activity) - kills the growth of mold and mildew: *Aspergillus niger (ATCC 6275)* (and the odors caused by them when applied to hard, non-porous environmental surfaces)

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Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), in the presence of 400 ppm hard water, 10% serum load and 10 minutes contact time, unless otherwise noted, VIREX™ II/ 256 kills the following:

Bacteria (Bactericidal Activity) - kills on hard non-porous inanimate surfaces:

- | | | |
|--|--|---|
| <i>Pseudomonas aeruginosa</i> , (ATCC 15442) | <i>Legionella pneumophila</i> , (ATCC 33153) | <i>Serratia liquefaciens</i> , (ATCC 14460) |
| <i>Staphylococcus aureus</i> , (ATCC 6538) | <i>Listeria monocytogenes</i> , (ATCC 15313) | <i>Serratia marcescens</i> , (ATCC 9103) |
| <i>Salmonella choleraesuis</i> , (ATCC 10708) | <i>Micrococcus luteus</i> , (ATCC 4698) | <i>Shigella dysenteriae</i> , (ATCC 29026) |
| <i>Acinetobacter calcoaceticus</i> , (ATCC 9957) | <i>Micrococcus sedentarius</i> , (ATCC 27573) | <i>Shigella flexneri</i> , (ATCC 25875) |
| <i>Bordetella bronchiseptica</i> , (ATCC 10580) | <i>Neisseria gonorrhoeae</i> , (ATCC 43069) | <i>Shigella sonnei</i> , (ATCC 25931) |
| <i>Burkholderia cepacia</i> , (ATCC 25416) | <i>Pasteurella multocida</i> , (ATCC 43137) | <i>Staphylococcus aureus</i> , (ATCC 25923) |
| <i>Campylobacter fetus</i> , (ATCC 27374) | <i>Proteus mirabilis</i> , (ATCC 9240) | <i>Staphylococcus aureus</i> (Toxic Shock), (ATCC 33586) |
| <i>Citrobacter freundii</i> , (ATCC 8090) | <i>Proteus vulgaris</i> , (ATCC 13315) | <i>Staphylococcus epidermidis</i> , (ATCC 14990) |
| <i>Enterobacter agglomerans</i> , (ATCC 27155) | <i>Pseudomonas cepacia</i> , (ATCC 25416) | <i>Staphylococcus haemolyticus</i> , (ATCC 29970) |
| <i>Enterobacter cloacae</i> , (ATCC 23355) | <i>Pseudomonas diminuta</i> , (ATCC 11568) | <i>Streptococcus agalactiae</i> , (ATCC 13813) |
| <i>Enterobacter liquefaciens</i> , (ATCC 14460) | <i>Pseudomonas fluorescens</i> , (ATCC 13525) | <i>Streptococcus faecalis</i> , (ATCC 19433) |
| <i>Enterococcus faecalis</i> , (ATCC 19433) | <i>Pseudomonas putida</i> , (ATCC 12633) | <i>Streptococcus mutans</i> , (ATCC 25175) |
| <i>Enterococcus hirae</i> , (ATCC 10541) | <i>Pseudomonas stutzeri</i> , (ATCC 17588) | <i>Streptococcus pyogenes</i> , (ATCC 19615) |
| <i>Escherichia coli</i> , (ATCC 11229) | <i>Salmonella choleraesuis pullorum</i> , (ATCC 19945) | <i>Streptococcus pyogenes</i> ("Strep A" - Flesh Eating Strain), (clinical isolate) |
| <i>Escherichia coli</i> O157:H7, (ATCC 43890) | <i>Salmonella enteritidis</i> , (ATCC 13076) | <i>Vibrio cholera</i> , (ATCC 11623) |
| <i>Flavobacterium meningosepticum</i> , (ATCC 13253) | <i>Salmonella gallinarum</i> , (ATCC 9184) | <i>Yersinia enterocolitica</i> , (ATCC 9610) |
| <i>Haemophilus influenza</i> , (ATCC 10211) | <i>Salmonella schottmuelleri</i> , (ATCC 10719) | |
| <i>Hafnia alvei</i> , (ATCC 13337) | <i>Salmonella typhi</i> , (ATCC 6539) | |
| <i>Klebsiella oxytoca</i> , (ATCC 13182) | <i>Salmonella typhimurium</i> , (ATCC 13311) | |
| <i>Klebsiella pneumoniae</i> , (ATCC 13883) | <i>Serratia grimesii</i> , (ATCC 14460) | |

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) - kills on hard non-porous inanimate surfaces:

- | | | |
|--|--|---|
| <i>E. coli</i> , (ATCC 55244); (resistant to Kanamycin) | <i>Klebsiella oxytoca</i> , (ATCC 15764); (resistant to Ampicillin, Dihydrostreptomycin) | <i>Staphylococcus aureus</i> (MRSA, GRSA, VRSA and others), (ATCC 33592 & 14154, CDC HIP-5836); (resistant to Methicillin [MRSA], Gentamicin [GRSA], Vancomycin [VRSA], Penicillin, Erythromycin, Streptomycin, Tetracycline) |
| <i>E. coli</i> O157:H7, (ATCC 47041); (resistant to Tetracycline) | <i>Micrococcus luteus</i> , (ATCC 14452); (resistant to Dihydrostreptomycin, Neomycin, Streptomycin) | <i>Streptococcus pneumoniae</i> , (ATCC 51915) (resistant to Penicillin [PRSP]) |
| <i>Enterococcus faecalis</i> , (ATCC 51299); (resistant to Vancomycin [VRE]) | <i>Micrococcus sedentarius</i> , (ATCC 27573); (resistant to Methicillin) | |

Viruses (*Virucidal Activity) – kills on hard non-porous inanimate surfaces:

- | | | |
|--|--|---|
| <i>HIV-1 (AIDS virus)**</i> , (HTLV-III _a) | <i>Herpes simplex Type 2</i> , (VR-734) | <i>Respiratory syncytial virus</i> , (VR-26) |
| <i>Cytomegalovirus</i> , (VR-538) | <i>Influenza Type A₂ (Hong Kong)</i> , (VR-544) | <i>Vaccinia virus</i> , (VR-119) |
| <i>Herpes simplex Type 1</i> , (VR-733) | <i>Parainfluenza Type 3</i> , (VR-93) | |
| (Veterinary viruses:) | | |
| <i>Avian Infectious bronchitis (IBV)</i> , (VR-22) | <i>Chlamydia psittaci</i> , (VR-125) | <i>New Castle disease</i> , (VR -108) |
| <i>Avian Influenza</i> , (VR -2072) | <i>Feline viral rhinotracheitis</i> , (VR- 636) | <i>Pseudorabies</i> , (VR- 135) |
| <i>Canine distemper</i> , (VR -128) | <i>Infectious bovine rhinotracheitis</i> , (VR -188) | <i>Transmissible gastroenteritis virus</i> (TGE), (U of Minn. Strain) |

Fungi/Yeast (Fungicidal and Yeast Activity) – kills on hard non-porous inanimate surfaces:

- | | |
|---|---|
| <i>Geotrichum candidum</i> , (ATCC 18301) | <i>Saccharomyces cerevisiae</i> , (ATCC 2601) |
|---|---|

Mold/Mildew (Mildewstatic Activity) - controls and prevents (inhibits) the growth of mold and mildew:
Aspergillus niger (ATCC 6275) (and the odors caused by them) when applied to hard, non-porous environmental surfaces.

**Tests performed using 1 minute contact time.

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Malodor(s) (Activity) (Odor) (Counteractancy) - eliminates (destroys) odors and odor-causing bacteria in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

Bactericidal Stability of Use-Dilution - Tests show VIREX™ II/ 256, when diluted in 400 ppm hard water and in the presence of 5% serum load, remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for up to 1 year in storage as long as it remains sealed. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, dry containers when diluting this product.

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear chemical splash-proof goggles or face shield, rubber gloves, protective clothing and protective footwear. Concentrate may be harmful if inhaled. Avoid breathing vapor. Concentrate is harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. *(After product is diluted in accordance with Directions For Use, causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Protective eyewear, clothing and gloves are not required. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.)*

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Immediately drink 1 to 2 glasses of water or milk. Do not induce vomiting or give anything by mouth to an unconscious person. Call a doctor or get medical attention. *(If diluted product gets: In Eyes, flush eyes with plenty of water. Call a physician, if irritation persists. If On Skin, wash with plenty of soap and water. Get medical attention if irritation persists.)*

Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not reuse empty container unless refilling from a larger container of the same product according to the refilling directions outlined previously. (Keep from freezing).

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

(Plastic Containers:)

If not being refilled with VIREX™ II/ 256, triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Sealed Dispenser Cartridges/Portion-Dose (ACCUMIX™) bottles/Tear-open pouches:)

Do not reuse, wrap empty container and put in trash. *[Note to Agency: Please note that neither dispenser cartridges nor portion-dose (ACCUMIX) bottles can be triple rinsed because they are closed sealed systems designed to reduce worker exposure to the concentrate.]*

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ENVIRONMENTAL HAZARDS (for containers of 5 gallons or 50 lbs. or more)

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PELIGRO

Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.

HAZARD RATING/CLASIFICACION EN CUANTO AL PELIGRO:

4=Very High

3=High

2=Moderate

1=Slight

0=Insignificant

Concentrate			1:256 Dilution	
HMIS	NFPA		HMIS	NFPA
3	3	Health/Salud	1	1
0	0	Flammibility/Inflamabilidad	0	0
0	0	Reactivity/Reactividad	0	0

4=Muy Alto

3=Alto

2=Moderado

1=Bajo

0=Insignificante

Questions? Comments:

Call 800-558-2332 Weekdays 8-5 Central Time (or) Write Customer Service Department, SC Johnson Professional, P.O. Box 902, Sturtevant WI 53177-0902.

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EPA Est. No. _____

(Lot number suffix (A) or (B) indicates appropriate establishment number.)

(MSDS Ref. No.xxxxxxxx)

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VIREX™ II/ 256 REFERENCE SHEET

When used as directed at a 1:256 dilution (1/2 oz. per gallon of water) (4mL/L), VIREX™ II/ 256 contains 660 ppm of active quaternary germicide making it highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms.

Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), in the presence of 400 ppm hard water, 10% serum and 10 minutes contact time, unless otherwise noted, VIREX™ II/ 256 kills the following:

Bacteria (Bactericidal Activity) - kills on hard non-porous inanimate surfaces:

- | | | |
|--|--|--|
| <i>Pseudomonas aeruginosa</i> , (ATCC 15442) | <i>Legionella pneumophila</i> , (ATCC 33153) | <i>Serratia liquefaciens</i> , (ATCC 14460) |
| <i>Staphylococcus aureus</i> , (ATCC 6538) | <i>Listeria monocytogenes</i> , (ATCC 15313) | <i>Serratia marcescens</i> , (ATCC 9103) |
| <i>Salmonella choleraesuis</i> , (ATCC 10708) | <i>Micrococcus luteus</i> , (ATCC 4698) | <i>Shigella dysenteriae</i> , (ATCC 29026) |
| <i>Acinetobacter calcoaceticus</i> , (ATCC 9957) | <i>Micrococcus sedentarius</i> , (ATCC 27573) | <i>Shigella flexneri</i> , (ATCC 25875) |
| <i>Bordetella bronchiseptica</i> , (ATCC 10580) | <i>Neisseria gonorrhoeae</i> , (ATCC 43069) | <i>Shigella sonnei</i> , (ATCC 25931) |
| <i>Zurkholderia cepacia</i> , (ATCC 25416) | <i>Pasteurella multocida</i> , (ATCC 43137) | <i>Staphylococcus aureus</i> (Toxic Shock), (ATCC 33586) |
| <i>Campylobacter fetus</i> , (ATCC 27374) | <i>Proteus mirabilis</i> , (ATCC 9240) | <i>Staphylococcus epidermidis</i> , (ATCC 14990) |
| <i>Citrobacter freundii</i> , (ATCC 8090) | <i>Proteus vulgaris</i> , (ATCC 13315) | <i>Staphylococcus haemolyticus</i> , (ATCC 29970) |
| <i>Enterobacter agglomerans</i> , (ATCC 27155) | <i>Pseudomonas cepacia</i> , (ATCC 25416) | <i>Streptococcus agalactiae</i> , (ATCC 13813) |
| <i>Enterobacter cloacae</i> , (ATCC 23355) | <i>Pseudomonas diminuta</i> , (ATCC 11568) | <i>Streptococcus faecalis</i> , (ATCC 19433) |
| <i>Enterobacter liquefaciens</i> , (ATCC 14460) | <i>Pseudomonas fluorescens</i> , (ATCC 13525) | <i>Streptococcus mutans</i> , (ATCC 25175) |
| <i>Enterococcus faecalis</i> , (ATCC 19433) | <i>Pseudomonas putida</i> , (ATCC 12633) | <i>Streptococcus pyogenes</i> , (ATCC 19615) |
| <i>Enterococcus hirae</i> , (ATCC 10541) | <i>Pseudomonas stutzeri</i> , (ATCC 17588) | <i>Streptococcus pyogenes</i> ("Strep A" -
Flesh Eating Strain), (clinical isolate) |
| <i>Escherichia coli</i> , (ATCC 11229) | <i>Salmonella choleraesuis pullorum</i> , (ATCC 19945) | <i>Vibrio cholera</i> , (ATCC 11623) |
| <i>Escherichia coli</i> 0157:H7, (ATCC 43890) | <i>Salmonella enteritidis</i> , (ATCC 13076) | <i>Yersinia enterocolitica</i> , (ATCC 9610) |
| <i>Flavobacterium meningosepticum</i> , (ATCC 13253) | <i>Salmonella gallinarum</i> , (ATCC 9184) | |
| <i>Haemophilus influenza</i> , (ATCC 10211) | <i>Salmonella schottmuelleri</i> , (ATCC 10719) | |
| <i>Hafnia alvei</i> , (ATCC 13337) | <i>Salmonella typhi</i> , (ATCC 6539) | |
| <i>Klebsiella oxytoca</i> , (ATCC 13182) | <i>Salmonella typhimurium</i> , (ATCC 13311) | |
| <i>Klebsiella pneumoniae</i> , (ATCC 13883) | <i>Serratia grimesii</i> , (ATCC 14460) | |

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) – kills on hard non-porous inanimate surfaces:

- | | | |
|---|---|--|
| <i>E. coli</i> , (ATCC 55244);
(resistant to Kanamycin) | <i>Klebsiella oxytoca</i> , (ATCC 15764);
(resistant to Ampicillin, Dihydrostreptomycin) | <i>Staphylococcus aureus</i> (MRSA, GRSA, VRSA and others), (ATCC 33592 & 14154, CDC HIP-5836);
(resistant to Methicillin [MRSA], Gentamicin [GRSA], Vancomycin [VRSA], Penicillin, Erythromycin, Streptomycin, Tetracycline) |
| <i>E. coli</i> 0157:H7, (ATCC 47041);
(resistant to Tetracycline) | <i>Micrococcus luteus</i> , (ATCC 14452);
(resistant to Dihydrostreptomycin, Neomycin, Streptomycin) | <i>Streptococcus pneumoniae</i> , (ATCC 51915)
(resistant to Penicillin [PRSP]) |
| <i>Enterococcus faecalis</i> , (ATCC 51299);
(resistant to Vancomycin [VRE]) | <i>Micrococcus sedentarius</i> , (ATCC 27573);
(resistant to Methicillin) | |

Viruses (*Virucidal Activity) – kills on hard non-porous inanimate surfaces:

- | | | |
|--|---|---|
| HIV-1 (AIDS virus)**, (HTLV-III _B) | Herpes simplex Type 2, (VR-734) | Respiratory syncytial virus, (VR-26) |
| Cytomegalovirus, (VR-538) | Influenza Type A ₂ (Hong Kong), (VR-544) | Vaccinia virus, (VR-119) |
| Herpes simplex Type 1, (VR-733) | Parainfluenza Type 3, (VR-93) | |
| (Veterinary viruses:) | | |
| Avian Infectious bronchitis (IBV), (VR-22) | Chlamydia psittaci, (VR-125) | New Castle disease, (VR-108) |
| Avian Influenza, (VR-2072) | Feline viral rhinotracheitis, (VR-636) | Pseudorabies, (VR-135) |
| Canine distemper, (VR-128) | Infectious bovine rhinotracheitis, (VR-188) | Transmissible gastroenteritis virus (TGE),
(U of Minn. Strain) |

Fungi/Yeast (Fungicidal and Yeast Activity) – kills on hard non-porous inanimate surfaces:

- | | |
|---|---|
| <i>Geotrichum candidum</i> , (ATCC 18301) | <i>Saccharomyces cerevisiae</i> , (ATCC 2601) |
|---|---|

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Mold/Mildew (Mildewstatic Activity) - controls and prevents (inhibits) the growth of mold and mildew: *Aspergillus niger* (ATCC 6275) (and the odors caused by them when applied to hard, non-porous environmental surfaces.

**Tests performed using 1 minute contact time.

Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), in the presence of 400 ppm hard water, 5% serum load and 10 minutes contact time, unless otherwise noted, VIREX™ II/ 256 kills the following:

Viruses (*Virucidal Activity) – kills on hard non-porous inanimate surfaces:

Adenovirus Type 2, (VR-2)

Fungi/Yeast (Fungicidal and Yeast Activity) – kills on hard non-porous inanimate surfaces:

Fungi:

Aspergillus niger, (ATCC 6275)

Trichophyton mentagrophytes

(athlete's foot fungus), (ATCC 9533)

Yeast:

Candida albicans, (ATCC 10231)

Mold/Mildew (Mildewcidal Activity) - kills the growth of mold and mildew: *Aspergillus niger* (ATCC 6275) (and the odors caused by them when applied to hard, non-porous environmental surfaces)

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria in restroom areas, behind and under sinks and counters, garbage cans and storage areas (and other places where bacterial growth can cause malodors).

Bactericidal Stability of Use-Dilution - Tests show VIREX™ II/ 256, when diluted in 400 ppm hard water, remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for up to 1 year in storage as long as it remains sealed. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, dry containers when diluting this product.

Questions? Comments:

Call 800-558-2332 Weekdays 8-5 Central Time (or) Write Customer Service Department, SC Johnson Professional, P.O. Box 902, Sturtevant WI 53177-0902.

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