

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 20 2003

Mr. Peter Fryatt
The Bullen Companies
P.O. Box 37
Folcroft, PA 19032-0037

Subject: Ready-to-Use Bathroom Cleaner and Disinfectant
EPA Registration No.: 1459-101
Submission Date: July 16, 2003
EPA Receipt Date: July 23, 2003

Dear Mr. Fryatt,

The following amendment submitted in connection with registration under FIFRA, as amended, acceptable with the conditions listed below.

- Update first aid statements per PR Notice 2001-1

Conditions

Revise the label as follows:

- 1. Qualify the following surfaces, porcelain, tiling, woodwork, as hard nonporous by stating "glazed" porcelain, "glazed" tiling, and "finished woodwork. You must delete the surfaces, grouting and leather, because they are considered porous, and data submitted to support this product's registration is for hard, nonporous surfaces only.
2. Revise the "Directions for Use" to reflect the following:
a. General Cleaning and Deodorizing: Hold spray nozzle 6 to 8" from the surface to cleaned. Thoroughly wet hard nonporous surface. Then wipe dry.
b. Disinfection/Virucidal: Hold trigger spray 6-8" from the hard nonporous surface. Thoroughly wet surfaces. Allow surface to remain wet for 10 minutes. Wipe clean with sponge, cloth, or mop or allow to air dry. For heavily soiled surfaces, a preliminary cleaning is required.

Rinse all food contact surfaces such as counters, tables, stovetops with potable water before reuse. Do not use on utensils, glassware, and dishes.

CONCURRENCES

Table with 3 rows (SYMBOL, SURNAME, DATE) and 8 columns for recording signatures and dates.

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- c. **Disinfect/Clean/Deodorize Toilet Bowls and Urinals:** Remove gross filth prior to disinfection. Push water out of the bowl by plunging head of bowl with bowl mop. Then ring bowl mop of excess water. Pour 1-2 oz of product directly into bowl. Scrub surface with bowl mop especially under the rim. Allow to stand for 10 minutes, then flush.
  - d. **Fungicidal:** Effective against Trichophyton mentagrophytes (Athelete's Fungus agent) in areas such as shower stalls and bathrooms. Follow Disinfection directions.
  - e. **Mold and Mildew Control:** Hold spray nozzle 6 to 8" from the surface to cleaned. Thoroughly wet hard nonporous surface. Allow surface to air dry. Repeat treatment every seven days or more often if new growth appears.
3. Revise the "Precautionary Statements" to read "*Causes eye and skin irritation. Do not get in eyes, on skin, or on clothing.* Wash thoroughly with soap and water after handling."
  4. Since your product does not meet the requirements to carry the "Note to Physician" language, delete it from the label. (You should refer to Label Manual 3<sup>rd</sup> Edition for guidance.)

**General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have any questions or comments regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

**CONCURRENCES**

<b>SYMBOL</b>								
<b>SURNAME</b>								
<b>DATE</b>								

# READY-TO-USE BATHROOM CLEANER AND DISINFECTANT

**GERMICIDE-CLEANER-DEODORANT-VIRUCIDE  
DISINFECTANT-FUNGICIDE-MILDEWSTAT**

Kills Staphylococci, Pseudomonas, Salmonella, Herpes Simplex Type 2 and  
the Athlete's Foot Organism on Environmental Surfaces  
Contains No Phosphates

**ACTIVE INGREDIENT:**  
 Alkyl (40% C<sub>12</sub>, 50% C<sub>14</sub>, 10% C<sub>16</sub>)  
 dimethyl benzyl ammonium chloride.....0.3%  
**INERT INGREDIENTS**.....99.7%  
**TOTAL INGREDIENTS**.....100.0%

EPA REG. NO. 1459-101

EPA EST. NO. 1459-PA-01

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See side panel for additional precautionary statements.

Manufactured by:  
THE BULLEN COMPANIES • Folcroft, PA 19032

NET CONTENTS: (Insert Here)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 20 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1459-101

**Ready-to-use, Non-Abrasive Formula**  
**DIRECTIONS FOR USE:**

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

An effective disinfectant, cleaner and deodorant for hospitals, homes, motels, hotels, schools, nursing homes, nurseries, factories, business and industrial buildings, restaurants, food plants, boats, campers and automobile and airplane interiors.

Cleans and deodorizes porcelain, tiling, grouting, stainless steel, enameled surfaces, woodwork, formica, leather, vinyl and plastic. Use it on counter tops, stove tops, exhaust fans, washable walls, sinks, shower stalls, toilet bowls, urinals, bed frames, vinyl, leather and plastic upholstery.

This product kills *Pseudomonas aeruginosa* (*Pseudomonas*), *Staphylococcus aureus* (*Staph*), *Salmonella choleraesuis* (*Salmonella*), Herpes Simplex Type 2 Virus (*Herpes*), HIV-1 virus (*AIDS virus*), Influenza Type A/Hong Kong (*Influenza*), *Trichophyton mentagrophytes* (*the Athlete's Foot Fungus*).

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

1. **FOR GENERAL CLEANING AND DEODORIZING:** Hold sprayer nozzle 6 to 8 inches from the surface to be cleaned. Thoroughly wet the area. Allow the solution to penetrate for about one minute and then wipe away the soil with a clean cloth or sponge. Do not breathe spray mist. The wiping cloth may be predampened with water or with this product. Apply this product to hard (inanimate) nonporous surfaces thoroughly wetting surfaces as recommended and required. For heavily soiled areas, a preliminary cleaning is required.

2. **FOR DISINFECTION:** Before disinfecting, pre-clean the surface as in Step 1 above. Then, apply enough fresh solution to thoroughly wet the surface. Allow the disinfecting solution to contact surfaces for 10 minutes before wiping or rinsing the treatment from the surfaces.

3. **TO DISINFECT, CLEAN AND DEODORIZE TOILET BOWLS AND URINALS:** (1) Push water out of the bowl by plunging head of bowl mop into the trap. Then squeeze water from the mop head by pressing it against the inside of the bowl. (2) Pour 1-2 oz. of this product over strands of mop and spread evenly over surface to be cleaned. Scrub surface with mop, especially under flush ring. (3) Allow surface to remain wet for at least 10 minutes before flushing...Preliminary cleaning is required to disinfect heavily soiled surfaces.

4. **FOR MILDEW:** Follow directions for disinfection. Repeat treatment every 2 weeks or when mildew growth first reappears. This product will effectively inhibit the growth of mildew and the odors caused by them when applied to hard, non-porous surfaces.

5. **DISINFECTION/VIRUCIDAL/MILDEW CONTROL/FUNGICIDAL DIRECTIONS:** Trigger spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist. Treated surfaces must remain wet for 10 minutes. Wipe clean with a cloth or tissue (wiper). A rinse with potable water is required for surfaces in direct contact with foods.

This product will effectively inhibit the growth of mildew and the odors caused by them when applied to hard, non-porous surfaces.

\*NOTE: This product may be used on food contact surfaces but surfaces must be thoroughly rinsed with potable water before they are permitted to recontact food.

\*KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTH CARE SETTINGS OR OTHER SETTINGS IN WHICH THERE IS AN EXPECTED LIKELIHOOD OF SOILING OF INANIMATE SURFACES/OBJECTS WITH BLOOD/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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) 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 blood/body fluids and during decontamination procedures.

**Cleaning Procedures:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant.

**Contact Time:** HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (room temperature). Use a 10-minute contact time for other viruses, fungi, and bacteria listed.

**Disposal of Infectious Materials:** Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**\*VIRUCIDAL Activity:** This product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A2-Asian (representative of the common flu virus), Herpes Simplex Type 2 (causative agent of fever blisters and mononucleosis), Adeno virus type 2 (causative agent of upper respiratory infections) and Vaccinia virus (representative of the pox virus group). Efficacy tests have demonstrated that this product is an effective bactericide, fungicide, and virucide\* in the presence of organic soil (5% blood serum).

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Causes eye irritation. Avoid contact with eyes, skin or clothing. Avoid contact with foods. Wash thoroughly with soap and water after handling.

**FIRST-AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

**If swallowed:** Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage.

*(If container size is 5 gallons or greater, use the following Environmental Hazards statements:)*

**ENVIRONMENTAL HAZARDS**

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 authority 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.

*(If container size is one gallon or less, use the following Storage and Disposal statements:)*

**STORAGE AND DISPOSAL**

Keep product under locked storage, inaccessible to small children. Do not reuse empty container. Rinse thoroughly, securely wrap empty container in several layers of newspaper and discard in trash.

*(If container size is greater than one gallon, use the following Storage and Disposal statements:)*

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE**

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

**PESTICIDE DISPOSAL**

Pesticide wastes are toxic. 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**

Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.