

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

OCT 20 2003

Subject: Bullen Ready-to-Use Disinfectant
EPA Registration No. 1459-72
Submission Date: July 15, 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, ceramic tiling and bathroom tiling, as hard nonporous by stating "glazed" ceramic tiling and "glazed" bathroom tiling.
2. Revise the "Fungicidal claim" by stating hard, *nonporous* surfaces and adding the statement, "*Follow disinfection directions.*"
3. Under "Disinfect/Clean/Deodorize, revise step 3 to read "*Wipe surfaces with cloth, sponge, or mop or allow to air dry. For heavily soiled surfaces, remove gross filth prior to disinfection. Rinse surfaces that come in contact with food such as tables and counters with potable water. Do not use on utensils, glasses, or dishes.*"
4. Since this product may be used in hospitals on bedframes, the following statement, the following MOU language from PR Notice 94-4 must be added to the label:

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

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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.

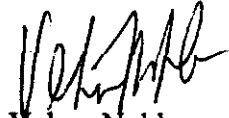
- 5. The "Precautionary Statements" must be updated to reflect language that supports the signal word, "Warning." Revise the statements to read *"Causes substantial but temporary eye injury. Harmful is absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (safety glasses, goggles, or faceshield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."*
- 6. 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 3rd 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)

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BULLEN READY TO USE DISINFECTANT

***DISINFECTS HERPES SIMPLEX TYPE 2 VIRUS
ON HARD INANIMATE NON-POROUS SURFACES
WILL NOT HARM CHROME, CARPETING OR CLOTHING**

ACTIVE INGREDIENTS:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	0.105%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	0.105%
INERT INGREDIENTS	99.790%
TOTAL	100.000%

EPA REG. NO. 1459-72

EPA EST. NO. 1459-PA-01

**KEEP OUT OF REACH OF CHILDREN
WARNING**

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. 1459-72

This product is designed for cleaning and disinfecting inanimate hard surfaces such as sink tops, tables, chairs, telephones, door knobs, light switches, hampers, cabinets, bed springs, toilet bowls, toilet seats, urinals, porcelain fixtures, ceramic tile floors and walls. Recommended for use in hospitals, nursing homes, institutions, offices, schools, motels and hotels.

This product is an effective odor counteractant for garbage storage areas, empty garbage bins and cans, basements, rest rooms and other areas which are prone to odors caused by microorganisms.

When used as directed, this product demonstrates effective disinfection against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa* meeting requirements for hospital use. Efficacy tests have demonstrated this product is an effective cleaner-disinfectant in presence of organic soil (5% blood serum).

This product is fungicidal against pathogenic fungi (*T. Mentagrophytes*), when used as directed on hard surfaces found in the bathroom, shower stall and locker room, or other clean, hard non-porous surfaces commonly contacted by bare feet.

DIRECTIONS FOR USE

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

TO DISINFECT, CLEAN AND DEODORIZE hard, non-porous surfaces such as toilet seats, bathroom tiles, fixtures, shower stalls, walls, sinks and bathtubs use this product full strength and proceed as follows:

(1) Apply with a cloth, mop or sponge or mechanical sprayer. When using a sprayer, hold container 6 to 8 inches from surface to be treated. (2) Apply liberally to cover area thoroughly. Allow to penetrate and remain wet for 10 minutes. No scrubbing necessary. (3) Pick up dirty solution with clean cloth, mop or sponge...For heavily soiled surfaces, remove gross soil before treatment.

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.

TO CONTROL MOLD AND MILDEW on hard, non-porous surfaces such as floors, walls, table tops: spray the surface to be treated, making sure to wet completely. Let air dry. Repeat applications at weekly intervals or when mildew growth reappears.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Keep Out of Reach of Children. Causes eye and skin irritation. Do not get in eyes, on skin or clothing. Harmful if swallowed.

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.