OCT 2 1 2002

Ms. Candice Rushton Regulatory Affairs Manager Betco Corporation 1001 Brown Avenue Toledo, Ohio 43607

Subject:

**Bol Maid** 

EPA Registration Number 4170-39 Application Dated July 25, 2002

# Dear Ms. Rushton:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comment.

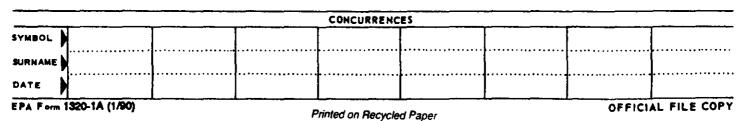
# **Proposed Amendment:**

revised First Aid statement PR Notice 2001-1

# **General Comments:**

Since this product is being used in hospitals to clean medical devices, the following statement must be added to the label:

"This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally steril 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.



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Please refer to PR Notice 94-4 for detailed information.

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely

Atlam Heyward Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

**Enclosure** 

## PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals DANGER

CORPLOSIVE: Causes irreversible eye damage or skin burns. Harmful if swallowed or adsorbed through the skin or inheled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or a face sheld. Wear protective clothing and rubber gloves. Wealt throughly with soop and water after handling. Remove contaminated clothing and wash clothing before reuse.

IF SWALLOWED: Call a 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 instructed to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. IF ON SKIN OR ON CLOTHING: immediately take off contaminated dothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Cell a poison control center or doctor for treatment advice. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice. 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.

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

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

### STORAGE AND DISPOSAL

Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash. In case of decomposition, isolate container (if possible) and flor of area with large amounts of water to dissolve all materials before distarding this container. Do not contaminate food or feed by storage, deposal or cleaning of equipment

### NE.OS No. 072



Manufactured By: C2002 Betco Corporation 1001 Brown Avenue Toledo, Ohio 43607-0127 U.S.A. All Rights Reserved. www.betco.com



# 07212

BOL MAID®

Hospital Disinfectant

Disinfectant Cleaner for Porcelain Toilet Bowls • Urinals - with Organic Soil Tolerance

Kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood body fluids.

## ACTIVE INGREDIENTS.

Octyl accyl a metnyl ammonium chloride............0.015 - ... Dipotyl aimethyl ammon-um chloride.......0.00615

Didecyl dimethyl ammonium chloride.......0.009-Alkyl (501, Cra. 401a Crg. 101a Crg.)

dimethyl benzyl ammonium chloride .........0.020% Hydrogen Chloride......9,000° INERT HIGHEDIENTS: ........50,950".

TOTAL 100.000 :

NET CONTENTS: 1 quart

# **KEEP OUT OF REACH** OF CHILDREN DANGER

See side panel for additional precautionary statements. FOR INSTITUTIONAL AND COMMERCIAL USE.

EPA EST. NO. 4170-0H-1 EPA REG. NO. 4170-39

**DESCRIPTION:** This disinfectant cleaner is designed for Hospital, General Industrial and Institutional use. It may be used to clean and disinfect toilet bowls, urinals, porcelain, sinks, bathtubs, shower tile and ceramic tile floors. Broad spectrum activity cleans, deodorizes and disinfects in one easy step.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this

product in a manner inconsistent with its labeling.
TO CLEAN AND DISINFECT TOILETS AND URINALS: Remove water from bowl by forcing it over the trap with a swab mop. Saturate swab with disinfectant cleaner and wet all surfaces thoroughly. It is most important to swab under rim of bowl or urinal to clean and disinfect water outlets. Allow disinfectant cleaner to remain for at least 10 minutes until all rust, scale and stains are loosened. Rinse by flushing. TO CLEAN AND DISINFECT SINKS, BATHTUBS, SHOWER STALLS, DRINKING FOUNTAINS AND CERAMIC TILE FLOORS: Dilute one part of this disinfectant cleaner with two parts water and apply to wet all surfaces thoroughly with swab mop, sponge, brush or doth. Allow disinfectant cleaner to remain for at least 10 minutes. Rinse after

FOR HEAVILY SOILED AREAS: A preliminary cleaning is required before disinfection can occur. At a dilution of one part disinfectant cleaner to two parts water, this product has shown broad spectrum activity against microorganisms commonly found in toilet bowls and uninals and has been evaluated in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution Test: PSEUDOMONAS AERUGINOSA, SALMONELLA CHOLERAESUIS, STAPHYLOCOCCUS AUREUS.

CHOLERAESUIS, STAPHYLOCOCCUS AUREUS.

Kills HIV-1 on predeaned environmental surfaces/objects previously solled with blood/body fluids in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of solling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled 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: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings. CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application. must be incrugify cleaned from surfaces and objects before application of this product. CONTACT TIME: Allow surface to remain wet for 10 minutes, DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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ACCEPTED with COMMENTS **EPA Letter Dated:** 

OCT 2 1 2002

Under the Federal Insecticide. Puncicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 4/70 -39

