UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4170-52

9-18-2002

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SEP 18 2002

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

Subject:

Pull

EPA Registration Number 4170-52 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 comments:

Proposed Amendment:

revised First Aid statement Per PR Notice 2001-1

General Comments:

- 1. Add the word "safety glasses" in parenthesis after the word face shield in the precautionary statement.
- 2. Refer to PR Notice 83-3 for appropriate storage and disposal statements.
- 3. Since this product is a hospital disinfectant, and is used in hospitals, the following statement must 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 for the bodycordiac contact mucous membranes but | | | | | | | | |
|--|-----|------------|--------------|-------------|-------------|---------------|--------------|--|
| SYMBOL | | which does | not ordinari | y penetrate | the blood b | arrier or oth | erwise enter | |
| SURNAME | . 1 | ļ | | | | | | |
| DATE | | | | | | | | |
| EPA For 1320-14 (100) | | | | | | | | |

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normally sterile areas of the body. This product may be used to preclean or decontaminate critical or sem-critical medical devices prior to sterilization or high level disinfection".

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 bearing the revised labeling.

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

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Adam Heyward

Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosure

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PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER POISON

CORROSIVE: Keep out of reach of children. Causes inversible eye damage or skin burns. May be fatal if swallowed, Harmful If adsorbed contage or surrounts, way be asset a sweatweet, name it associated through skin or inhaled. Do not get in eyes, on skin or on clothing, Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing and nubber gloves, Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately To 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 clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call 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 ringing 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 castric lavage.

STORAGE AND DISPOSAL

Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash.

M30S No. 071



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







DESCRIPTION: This disinfectant toilet bowl and urinal cleaner is designed for Hospital, General industrial, and institutional use (schools, factories, nursing homes). Its broad spectrum activity cleans, descales, 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 TOILET BOWLS AND URINALS: Remove water from bowl by forcing it over the trap with a swab mop. Saturate swab mop with cleaner/disinfectant and wet all surfaces thoroughly. It is most important to swab under rim of bowl or urinal to clean and disinfect water outlets. Allow cleaner/disinfectant to remain for at least 10 minutes until all rust, scale, and stains are loosened. Rinse by flushing. For heavily soiled areas a preliminary cleaning is required. At a dilution of one part cleaner/disinfectant to 3 parts water, this product has shown broad spectrum activity against microorganisms commonly found in toilet bowis and urinals, and has been evaluated in the presence of 5% serum and found to be effective against the in the presence of 5% serum and found to be effective against the tollowing organisms by the AOAC Use-Dilution test PSEUDOMONAS AERUGINOSA, SALMONELLA CHOLERAESUIS, STAPHYLOCOCCUS AUREUS. Kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes) or 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: 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 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:

SEP 18 2002

Under the Federal Insecticide, Funcicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 4/70-52