

4170-52

9-18-2002

4/3

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 body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter

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2/3

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.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

