

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Betco Corporation
 1001 Brown Avenue
 P.O. Box 3127
 Toledo, Ohio 43607

AUG 28 1991

Attention: Timothy J. Wright

Gentlemen:

Subject: ND/316
 EPA Registration Number 4170-76
 Your submission Dated April 16, 1991
 EPA Received Date April 24, 1991

The amendment referred to above, submitted in connection with registration under FIFRA is acceptable provided that you make the following changes:

- a. Under the heading "Contact Time" revise the statement "Effective against HIV-1 (Aids Virus) ... to read " 4 minutes at room temperature (20-25 degrees C) ."
- b. Include complete nomenclature of Influenza A/ Hong Kong Virus.
- c. Include directions for use in farm and poultry premises. Refer to the attached DIS/TSS-18 and DIS/TSS-19 enclosures.
- d. Change "Adenovirus Type IV" to read "Adenovirus Type 4".
- e. There are two strains of Rubella. Specify which one it is. Change "Trichophyton interdigitale" to read "Trichophyton Mentogrophytes."
- f. Change "porcelain" to read "glazed porcelain".
- g. The label needs to indicate the types of plastic (polypropylene, polystyrene, polyvinyl, chloride, etc.)
- h. Under the heading "Description", in the second paragraph revise the phrase, " according to the AOAC Use Dilution, current edition.... " to read " according to the AOAC Use Dilution Method (specify edition and year in the parenthesis)...".

CONCURRENCES

SYMBOL	DATE	INITIALS	REMARKS	DATE	INITIALS	REMARKS	DATE	INITIALS	REMARKS

j. Delete the word "Concentrated" wherever it appears on the labeling.


k. Change "Herpes Simplex Type I" and "Herpes Simplex Type II" to read " Herpes Simplex Type 1" and "Herpes Simplex Type 2."

A stamped copy is enclosed for your records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of the product constitutes acceptance of these conditions.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-557-3966.

Sincerely Yours,

John H. Lee 
Product Manager-31
Antimicrobial Program Branch
Registration Division (H7505-C)

BEST AVAILABLE COPY

ND/316

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

4170-76

**Disinfectant
Detergent/Deodorant**
Pseudomonacidal, Staphylocidal,
Salmonellacidal, Fungicidal,
Virucidal*

Authorized by the USDA for use in
federally inspected meat and poultry
plants.



ACTIVE INGREDIENTS:
Didecyl dimethyl ammonium
n-Alkyl (C14 50%, C12 40%)
benzyl ammonium chloride
INERT INGREDIENTS
TOTAL

KEEP OUT OF REACH OF CHILDREN
CAUTION
See side panel for
precautionary statements
FOR INDUSTRIAL
INSTITUTIONS

EPA EST. NO. 4170-
EPA REG. NO. 4170-

316

DESCRIPTION

A concentrated, multi-purpose germicidal detergent and deodorant effective in hard water up to 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum. Disinfects, cleans, and deodorizes in one labor saving step. Recommended for use in hospitals, nursing homes, schools, colleges, veterinary clinics, animal life science laboratories, federally inspected meat and poultry establishments, equine farms, livery shops, pet shops, airports, kennels, hotels & motels, poultry & turkey farms, dairy farms & hog farms, breeding & grooming establishments.

Bactericidal at 1:64 dilution (2 ounces per gallon of water) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* according to the current AOAC Use Dilution Test method, modified in the presence of 400 ppm synthetic hard water (calculated as CaCO₃) plus 5% organic serum.

Fungicidal against *Trichophyton interdigitale* and *Candida albicans* according to the AOAC fungicidal test, modified in the presence of 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum at a 1:64 dilution.

Virucidal against HIV-1 (AIDS virus), Influenza A/Hong Kong, Herpes simplex Type I, Herpes simplex Type II, Vaccinia, Rubella, Adenovirus Type IV, Canine parvovirus, Canine distemper, Feline panleukopenia, Feline parvovirus, Feline leukemia, Rabies, Porcine parvovirus, Pseudorabies, Infectious bovine rhinotracheitis, and Infectious bronchitis (Avian MV) according to the virucidal qualification, modified in the presence of 400 ppm hard water plus 5% organic serum at a 1:64 dilution.

**PRE CAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Keep out of reach of children. Causes eye irritation. Avoid contact with eyes. Wash thoroughly after handling.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes call a physician.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** PLASTIC CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. **GENERAL:** Consult Federal, state or local disposal authorities for approved alternative procedures such as limited open burning.

MILDEWSIATIC INSTRUCTIONS:

Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply solution (2 ounces per gallon of water) with cloth, mop, sponge, or spray making sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

5 GALLON

Manufactured By:
Betco Corp., Toledo, Ohio 43607

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DIRECTIONS FOR USE

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

For use on hard non-porous surfaces such as floors, walls, metal surfaces, porcelain, and plastic surfaces. Remove gross dirt and heavy soil deposits then thoroughly wet surfaces. Use 2 ounces or 1/4 cup per gallon of water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, or cloth as well as spraying or soaking. The recommended use solution is prepared fresh for each use then discarded. Rinsing is not necessary unless floors are to be waxed or polished.

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 (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 body fluids, blood, and decontamination procedures.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

CONTACT TIME: Effective against HIV-1 (AIDS virus) on hard non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at a 1:64 dilution (providing 600 ppm of active quaternary) in 400 ppm CaCO₃ hard water for a contact time of 4 minutes at room temperature (20-25°C). Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses claimed (Noted on labeling).

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

A concentrated multi-purpose germicidal detergent and deodorant effective in hard water up to 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum. Disinfects, cleans, and deodorizes in one labor saving step. Effective against the following pathogenic bacteria according to the AOAC Use Dilution, current edition, modified in the presence of 400 ppm synthetic hard water (calculated as CaCO₃) plus 5% organic serum.

- | | |
|---------------------------------------|-----------------------------------|
| <i>Pseudomonas aeruginosa</i> | <i>Proteus mirabilis</i> |
| <i>Staphylococcus aureus</i> | <i>Proteus vulgaris</i> |
| <i>Salmonella choleraesuis</i> | <i>Salmonella typhi</i> |
| <i>Shigella boydii</i> | <i>Salmonella typhimurium</i> |
| <i>Shigella flexneri</i> | <i>Serratia marcescens</i> |
| <i>E. coli</i> | <i>Shigella flexneri</i> |
| <i>E. coli (antibiotic resistant)</i> | <i>Shigella sonnei</i> |
| <i>Enterobacter aerogenes</i> | <i>Staphylococcus aureus</i> |
| <i>Enterobacter cloacae</i> | (antibiotic resistant) |
| <i>Fusobacterium necrophorum</i> | <i>Staphylococcus epidermidis</i> |
| <i>Klebsiella pneumoniae</i> | (antibiotic resistant) |
| <i>Klebsiella pneumoniae</i> | <i>Streptococcus faecalis</i> |
| (antibiotic resistant) | (antibiotic resistant) |
| <i>Pasteurella multocida</i> | <i>Streptococcus faecalis</i> |
| <i>Pseudomonas aeruginosa</i> | <i>Streptococcus pyogenes</i> |

ACCEPTED
EPA FORM 855
EPA Form Date:
AUG 28 1991

4170-76