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Calgon Vestal Laboratories
P. O. Box 147
Saint Paul, MN 63166

MAR 23 1994

Attention: Ann Vu

Gentlemen:

Subject: Process NPD
EPA Registration Number 1043-90
Your Submission Dated October 8, 1993
EPA Received Date October 25, 1993

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, to add additional bactericidal claims with efficacy data and revised proposed label, is acceptable.

The submitted data are acceptable to support effectiveness of the product as a one-step disinfectant against Pseudomonas aeruginosa ATCC 13388 on hard, non-porous surfaces at a 1:128 dilution in the presence of 5% organic soil (serum) and 400 ppm CaCO₃ hard water for a contact time of 3 minutes at 20 degrees Celsius.

The following labeling revisions must be made:

1. On the front panel, under the product name, change "virucuide" to "virucide".
2. Under the heading: GERMICIDE, the dilution to be used against Pseudomonas aeruginosa must be specified.

A stamped label is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,

Marshall Swindell
Acting Product Manager-31
Antimicrobial Program Branch
Registration Division(7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,

Marshall Swindell
Acting Product Manager-31
Antimicrobial Program Branch
Registration Division(7505-C)

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ACCEPTED
with Comments

MAR 29 1994

1043-90

Process NPD™

ONE-STEP GERMICIDAL DETERGENT

E.P.A. Reg. No. 1043-90

Germicide•Fungicide•Virucide•Detergent•Deodorizer•Concentrate

Active Ingredients

Octyl decyl dimethyl ammonium chloride	4.60%
Dioctyl dimethyl ammonium chloride	2.30%
Didecyl dimethyl ammonium chloride	2.30%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	6.14%
Inert Ingredients	84.66%

FOR INSTITUTIONAL, INDUSTRIAL AND AGRICULTURAL USE

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. For skin contact, flush with water. See side panel for additional precautionary statements.

**CONTENTS: One U.S. Gallon
(3.78 Liters)**

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Precautionary Statements

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Concentrate corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Concentrate may be fatal if absorbed through the skin.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. For skin contact, flush thoroughly with water. Remove and wash contaminated clothing before reuse. If swallowed, drink a large quantity of egg white, gelatin solution, or water. Avoid alcohol. Do not induce vomiting. Call a physician immediately. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DIRECTIONS FOR USE

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

CLEANING AND DISINFECTING: Add one-half ounce (15cc) to each measured gallon of water used. Always add this product to premeasured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop, brush or coarse spray using normal cleaning methods. Thoroughly wet all surfaces to be cleaned, then remove excess solution with a wrung-out applicator. Treated surfaces should remain wet for ten minutes. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when it becomes dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY FACILITY CLEANING AND DISINFECTING: Remove or cover all food, feedstuffs, packaging materials and livestock. Remove all litter, manure and other debris from floors and walls; scrape if necessary. Empty all troughs, racks, feeders and waterers. Saturate all surfaces with a 1:256 solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen adhering soils. Allow to soak for 10 minutes, then pick up excess with a wrung-out applicator. Flush feeders and waterers with potable water after disinfecting. Drain all surfaces, ventilate buildings and allow to air-dry before use or rehousing animals.

CLEANING AND DISINFECTING FOOD PREPARATION AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

ANTIVIRUCIDAL ACTIVITY AGAINST CANINE PARVOVIRUS, FELINE CALICIVIRUS AND INFECTIOUS BURSAL DISEASE: Dilute product 1:64 (2 ounces per gallon) and apply as directed above.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures to sanitize surfaces in research and manufacturing facilities, in poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (1/2 ounce per gallon of water). Remove all animals and feed from areas to be fogged. Remove all litter and manure from surfaces or areas traversed by animals. Empty all trough, racks and other feeding and watering appliances. Thoroughly clean all surfaces. Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or cover any food or packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with Process NPD at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings 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 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Wear appropriate barrier protection such as 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 1:256 use-solution (1/2 ounce per gallon). Prepare and apply solution as directed in paragraph above.

CONTACT TIME: While the HIV-1 virus is inactivated in 30 seconds, use a 10 minute contact time for disinfection of all organisms on this label.

INFECTIOUS MATERIALS DISPOSAL: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposals.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: This germicide, its solutions or rinsings from empty containers should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burnings. If frozen thaw and remix before use.

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in USA
MAR 29 1994

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This product is a research-developed hard water effective, phosphate-free concentrated germicidal detergent system designed to simultaneously clean, disinfect and deodorize in the presence of 5% organic soil (serum) when diluted with 400 ppm hard water.

It is intended for use on washable hard non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment in pharmaceutical and cosmetic facilities and in food processing, preparation and service facilities, in animal husbandry, poultry and food processing facilities, veterinary clinics, animal research facilities, and in other indoor areas where infectious contamination control is a necessity.

Use the use-solution for the cleaning and disinfection of metal surfaces such as stainless or galvanized steel and chrome, porcelain, plastics, glass, tile, washable painted or varnished surfaces, concrete, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo or other combination-type floors.

Germicide: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. Choleraesuis*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (1/2 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20° C.

It has also been shown in the A.O.A.C. Use-Dilution Test, when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 solution (1/2 ounce per 1 gallon of water) in the presence of 5% organic soil (serum), 10 minutes at 20° C to inactivate:

Acinetobacter calcoaceticus, ATCC 19606
Bordetella avium, ATCC 35086
Bordetella bronchiseptica, ATCC 10580
Campylobacter jejuni, ATCC 29428
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Listeria monocytogenes, ATCC 19111
Mycoplasma gallisepticum, ATCC 19610
Pasteurella multocida, ATCC 27853
Proteus vulgaris, ATCC 13315

Pseudomonas aeruginosa, ATCC 9027
Pseudomonas cepacia, ATCC 25609
Salmonella enteritidis, ATCC 13076
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus aureus, (MRSA, Multiply)
(Methicillin)-Resistant Clinical Isolate
Staphylococcus epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433
Streptococcus pyogenes, ATCC 19615

Process NPD is effective in 3 minutes on hard surfaces against *Pseudomonas aeruginosa*, ATCC 13388, according to the A.O.A.C. Use Dilution Test in the presence of 5% organic soil (serum) and 400 ppm hard water at 20° C.

Fungicide: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (1/2 ounce per 1 gallon) solution, in the presence of 5% added organic soil (serum), 10 minutes at 20° C.

***Virucide:** Process NPD is effective against the following viruses according to the EPA-approved virucidal assay method when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per gallon) solution, in the presence of 5% organic soil (serum) in 10 minutes at 20-25° C on hard non-porous environmental surfaces:

Canine distemper, ATCC-128
Canine parainfluenza, ATCC VR-399
Chlamydia psittaci (Feline Pneumonitis)
Feline rhinotracheitis, ATCC VR-636
Herpes simplex Types 1 and 2
Infectious bronchitis, ATCC VR-22

Infectious laryngotracheitis, ATCC VR-783
Influenza A₂ (Japan-305)
Marek's Disease, ATCC VR-2002
Mouse hepatitis, ATCC VR-764
Newcastle Disease, ATCC VR-119
Vaccinia virus

#Effective against Canine parvovirus, ATCC VR-953, Feline calicivirus, ATCC VR-782, Infectious bursal disease (Lukert strain) according to the EPA-approved virucidal assay method when diluted 1:64 in 400 ppm hard water in 5% organic soil (serum) in 10 minutes at 20-25° C on hard non-porous environmental surfaces.

†When tested by an EPA-approved Dilution Method the HIV-1 (AIDS) virus, with added 5% organic soil (serum) was completely inactivated by a 1:256 (1/2 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 30 seconds at 20° C. Although efficacy at 30 seconds contact time has been shown to be adequate against HIV-1 this time would not be sufficient for other organisms. Use a 10 minute contact time for disinfection against all of the organisms claimed.

Odor Control: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors. Also eliminates unpleasant smelling soils.

APPROVED
MAY 24 1984
1043-90

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