

3838-53

06/04/1999

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 04 1999

Essential Industries, Inc
P.O. Box 12
Merton, WI 53056-0012

Subject: Nutra-Cide 256
EPA Registration No. 3838-53
Your Amendment Dated: 3/2/99

Attention: Ms. Dawn Zellmer,
Compliance Specialist

The amendment referenced above, submitted in connection with registration under FIFRA 3 (c) (7) (a) is acceptable provided you address the following comments prior to releasing this product for shipment.

The addition of the organisms, Methicillin resistant *Staphylococcus aureus*, *Streptococcus pyogenes* (Clinical-Flesh Eating Strain M3), *Enterococcus faecalis* VRE, *Trichophyton mentagrophytes*, and HIV-2, to the label is acceptable.

Based on a review of the Stepan Acute Toxicology studies cited in support of this amended registration, the following acute toxicology categories are assigned.

<u>GUIDELINES</u>	<u>STUDIES</u>	<u>CATEGORY</u>
81-1	acute oral toxicity	III
81-2	acute dermal toxicity	II
81-4	primary eye irritation	I
81-5	primary skin irritation	I
81-6	dermal sensitization	Non-sensitizer

Therefore, your precautionary labeling must be revised as follows:

CONCURRENCES

SYMBOL	7500						
SURNAME	Campbell						
DATE	6/4/99						

Precautionary Statements Revisions:

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, safety glasses or faceshield), rubber gloves, and protective clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

Practical Statements of Treatment Revisions:

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink a large quantities of water. Avoid alcohol.

A stamped copy of the label is enclosed for your records. Please submit one (1) copy of the final printed label before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510C)

NUTRA-CIDE 256

KEEP OUT OF THE REACH OF CHILDREN

DANGER

For Commercial, Industrial and Institutional Use Only
See Side Panels For Additional Precautionary Statements

Disinfectant · Cleaner · Deodorizer · Virucide*

EPA Reg. No. 3838-53 · EPA Est. No. 3838-WI-1

ACTIVE INGREDIENTS

Disinfectant	25.6%
Cleaner	10.0%
Deodorizer	10.0%
Virucide	10.0%
Other	44.4%

INERT INGREDIENTS

TOTAL



**ESSENTIAL
INDUSTRIES**



254DN

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

JUN 4 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

3838-53

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools, restaurants, and other institutions where housekeeping is of prime importance in controlling cross-contamination from treated surfaces.

This product, when used as directed, is formulated to disinfect hard, non-porous, inanimate, environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets. For larger areas such as operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfecting.

This product deodorizes those areas which generally are hard to keep fresh-smelling such as garbage storage areas, empty garbage bins and cans, toilet bowls, and other areas which are prone to odors caused by microorganisms.

This product is formulated to a neutral pH and will not dull high-gloss floor finishes with repeated use.

DISINFECTION: To disinfect inanimate, hard, non-porous surfaces add 1/2 ounce of this product per gallon of water. Apply solution with a mop, cloth, sponge, or hand-pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls, flush toilet, and 1/2 ounce of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

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 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

DEODORIZATION: To deodorize, apply this product as indicated under the heading DISINFECTION.

BACTERICIDAL ACTIVITY: At the 1/2 ounce per gallon dilution, this product demonstrates effective disinfectant activity against the organisms *Pseudomonas aeruginosa* PRD-10, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Staphylococcus aureus* (clinical isolate), *Bordetella bronchiseptica*, *Corynebacterium ammoniagenes*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterobacter cloacae* (clinical isolate), *Enterococcus faecalis*, *Enterococcus faecalis*

(clinical isolate), *Escherichia coli*, *Escherichia coli* (clinical isolate), *Fusobacterium necrophorum*, *Klebsiella pneumoniae* subsp. *pneumoniae*, *Lactobacillus casei* subsp. *rhamnosus*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus vulgaris*, *Proteus mirabilis* ATCC 9921, *Proteus mirabilis* ATCC 25933, *Salmonella choleraesuis* subsp. *choleraesuis* serotype paratyphi B, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhi, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhimurium, *Salmonella choleraesuis* subsp. *choleraesuis* serotype pullorum, *Serratia marcescens*, *Shigella sonnei*, *Shigella flexneri* Type 2b, *Shigella dysenteriae*, *Staphylococcus aureus* subsp. *aureus*, Methicillin resistant *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus epidermidis* (clinical isolate), *Streptococcus pyogenes* (Clinical - Flesh Eating Strain BIRD M3), *Streptococcus pyogenes* Group A, *Xanthomonas maltophilia* (clinical isolate) and Vancomycin resistant *Enterococcus faecalis* (ATCC 51575).

FUNGICIDAL ACTIVITY: At the 1/2 ounce per gallon dilution, this product demonstrates effective fungicidal activity against the pathogenic fungi *Trichophyton mentagrophytes*, *Candida albicans* and *Aspergillus niger*.

VIRUCIDAL ACTIVITY: This product, when used on environmental, inanimate hard non-porous surfaces at 1/2 ounce per gallon of water, exhibits effective virucidal activity against Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital disease), Influenza A2/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus and Canine Distemper.

KILLS HIV-1 AND HIV-2 ON PRE-CLEANED 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 and Type 2 (HIV-1 or HIV-2) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HIV-2 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.

Net Contents: One Gallon (3.8 Liters)

PRECAUTIONS HAZARDS TO HUMANS

DANGER. KEEP OUT OF REACH OF CHILDREN in eyes, on skin or on clothing. Wear goggles. Harmful or fatal if swallowed. Avoid contamination before reuse. Wash thoroughly with soap and water.

STATEMENT OF PRACTICAL TREATMENT: In case of ingestion, drink plenty of water for at least 15 minutes. For eye contact, flush with water or saline solution; or if these are not available, flush with water. Contact your physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage.

STORAGE

DO NOT CONTAMINATE WATER, FOOD, OR FEEDSTUFFS.
STORAGE: Store in a dry place no lower in temperature than 40°F.
CONTAINER DISPOSAL: Do not reuse empty container.
PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. If a spray or mixture or rinsate is a violation of Federal law, it is the responsibility of the user to dispose of it according to label instructions, contact your State Hazardous Waste representative at the nearest:

Essential

P.O. Box 12 · Merton, Wisconsin

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