

PM-32

Reg # 63281-8

194

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 12 1995

RSP Private Label Packaging
969 East Tipton Street
Huntington, IN 46750

Attention: Sally Hayes
Manager, Regulatory Affairs

Subject: Phenocide 128
Your File Symbol Number 63281-8
Your Submission Dated January 24, 1994
EPA Receive Date January 31, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, to update your label will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

This product must have the FDA/EPA MOU disclaimer added to the label: It should read as follows:

"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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection."


A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

194

If you have any questions concerning this letter, please contact me at (703) 305-7964.

Sincerely,


Ruth Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

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DILUTION: 1 to 128

ONE OUNCE PER GALLON

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS:

USES: For use on hard, non-porous surfaces such as floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring and lavatory fixtures. For use in hospitals, nursing homes, schools, colleges, medical and dental offices, farms, hog farms, equine farms, poultry and turkey farms, federally inspected meat and poultry plants, tack shops, kennels, pet shops, veterinary clinics, and animal life science laboratories. This includes barns, calf pens, laying operations, breeder operations, hatcheries, agricultural buildings and premises, live haul equipment, trucks, foot baths, and meat and poultry processing plants.

APPLICATIONS: Use 1 ounce of Phenocide 128 per gallon of water for a minimum contact time of 10 minutes in a single application. For disinfecting, remove gross filth and heavy soil deposits, then thoroughly wet surfaces. Phenocide 128 is extremely versatile and can be applied with a mop, sponge, or cloth as well as soaking or used as a holding solution. Thoroughly wet surfaces with the recommended use solution for at least 10 minutes. The recommended use solution is used once and discarded on a daily basis. Rinsing is not necessary on floor surfaces unless floors are to be waxed or polished. Tuberculocidal effectiveness is in 10 minutes at 20°C.

HATCHERY: Can be used for cleaning, disinfecting and deodorizing floors, walls and equipment throughout the hatchery. This includes incubators, setters, and racks. Add 1 ounce per gallon of water. Hot or cold water may be used. Remove loose waste, gross filth, and heavy soil deposits prior to disinfecting. Repeat with fresh solution to disinfect.

USDA: For use in federally inspected meat and poultry plants on all surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

MAY 12 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide
registered under EPA Reg. No.
63281-8

**Phenocide 128
GERMICIDAL DETERGENT**

**Cleans, Disinfects & Deodorizes
- Pleasant Fragrance**

**PSEUDOMONACIDAL STAPHYLOCIDAL
*VIRUCIDAL FUNGICIDAL TUBERCULOCIDAL**

Phenocide 128 is a multi-purpose germicidal detergent proven effective by the AOAC Use-Dilution Method in 400 ppm hard water (calculated as CaCO₃) in the presence of 5% organic bioload (Fetal Bovine Serum). Phenocide 128's formula disinfects, cleans, and deodorizes in one labor-saving step. Phenocide 128 is effective against the following pathogenic organisms:

- | | |
|---------------------------|------------------------------------|
| Pseudomonas aeruginosa | *HIV-1 (AIDS virus) |
| Salmonella choleraesuis | *Rubella |
| † Staphylococcus aureus | *Adenovirus Type 2 |
| Enterobacter aerogenes | *Herpes Simplex Type 2 |
| † Enterobacter cloacae | *Human rhinovirus Type 38 |
| **Enterococcus sp. | *Influenza Type A/Mich |
| Escherichia coli | *Polio I virus |
| Klebsiella pneumoniae | *Vaccinia |
| Mycobacterium bovis | *Avian Influenza |
| † Proteus mirabilis | *Canine parvovirus |
| Proteus vulgaris | *Feline leukemia |
| Providencia rettgeri | *Feline picornavirus |
| Pseudomonas cepacia | *Infectious Bovine Rhinotracheitis |
| **Pseudomonas maltophilia | *Newcastle Disease Virus |
| Salmonella typhi | |
| Salmonella typhimurium | Candida albicans |
| Serratia marcescens | Trichophyton mentagrophytes |
| Shigella flexneri | |
| † Streptococcus faecalis | |
| Streptococcus pyogenes | |

*Tested against antibiotic resistant strain only.
†Tested against standard ATCC strains and antibiotic resistant strains.

ACTIVE INGREDIENTS:

o-benzyl-p-chlorophenol	4.75%
o-phenylphenol	4.75%
INERT INGREDIENTS:	90.50%
Total	100.0%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

(See safe panel for additional precautionary and practical treatment statements)

CONTENTS

EPA Reg No 63281-8 EPA Est. No 63281-IN-1
RSP Private Label Packaging
969 East Tipton Street
Huntington, IN 46750
(219) 356-7073

KILLS HIV ON SURFACES/OBJECTS & FLUIDS in health care areas where there is an expected likelihood of spillage and in which the surface fluids can be associated with immunodeficiency virus. **SPECIAL INSTRUCTIONS:** DECONTAMINATION SURFACES/OBJECTS & PERSONAL PROTECTIVE CLOTHING during all cleaning operations. Thoroughly cleaned from Phenocide 128. This cleaning method including this product. **CONTACT TIME:** HIV-1 requires 10 minutes of contact at room temperature for other common types of viruses. **DISPOSAL OF INFECTIOUS FLUIDS:** should be autoclaved or otherwise rendered non-infectious before disposal.

STATEMENT OF PRECAUTIONS: In case of skin contact, wash with soap and water. In case of eye contact, immediately flush with water and seek prompt medical attention. Avoid alcohol. **NOTE TO PHYSICIAN:** Phenocide 128 may cause depression, and convulsions. **PRECAUTIONARY STATEMENT:** HAZARDS TO HUMANS AND DOMESTIC ANIMALS: **DANGER**

Corrosive. Causes eye irritation. Causes skin irritation. Causes clothing damage. Wash thoroughly with soap and water. Avoid contamination of food, water, and feed.

STORAGE

PROHIBITIONS: Do not contaminate water. Dumping is prohibited. **PESTICIDE DISPOSAL:** Pesticide wastes are acutely toxic. Pesticide wastes, spray mixtures, and containers cannot be disposed of in landfills. Contact your State Pesticide or Environmental Control Agency for more information. **CONTAINER DISPOSAL:** Triple rinse (or equivalent). Puncture and dispose of wastes in accordance with state and local authorities.

LIVESTOCK, TURKEY, AND POULTRY HOUSE DISINFECTANT

DILUTION: 1:128

ONE OUNCE PER GALLON

DIRECTIONS FOR USE

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
8. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(Refer to label for precautionary and practical treatment statements.)

[To be used as an insert or hang tag or inserted on label]

REGISTERED
with COMMENTS
in EPA Letter Dated

010594

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide
manufactured under EPA Reg. No.
62222

4