

FEB 10 1989

Dubois Chemicals, Inc.
3630 East Kemper Road
Sharonville, OH 45241

Gentlemen:

Subject: Response to Tuberculocidal Data Call-In Notice
GSC
EPA Registration No. 5736-24
Your Submission Dated July 20, 1988

This is in response to your resubmission in regard to the Tuberculocidal Data Call-In (TB DCI) Notice for the subject product.

The submitted data show effectiveness of the product as a tuberculocide by the AOAC Tuberculocidal Activity Method (II. Confirmative In Vitro Test) (unmodified) in 10 minutes at 20 °C at a dilution of 1:100 when used to thoroughly wet previously cleaned, hard, nonporous, inanimate, surfaces.

The labeling (label and Technical Data Sheet), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable in support of the TB DCI Notice provided that you:

1. Make the following revisions before you release the product for shipment bearing the amended labeling.
 - a. Delete "Only for sale to use and storage by service persons."
 - b. Include on the front panel of the one gallon label the referral statement "See back panel for additional precautions and Statement of Practical Treatment."
 - c. On the back panel, first paragraph (one gallon label), revise the wording "as a possible breeding place for reinfection . . ." to read "as a possible site for cross contamination"
 - d. On the back panel, under "For Laboratory Glassware and Surgical Instruments (one gallon label), revise "Use GSC at 1:28 . . ." to read "Use GSC at 1:128"

57158;I;Douglas;K-10;KEMCO;2/2/89;2/13/89;AS;VO;AS

CONCURRENCES

SYMBOL								
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- e. Under the product general description on the Technical Bulletin, wording should be included to indicate that product usage is for "precleaned hard, nonporous, inanimate surfaces." The current wording in the general description appears to imply that the product is effective as a disinfectant-cleaner. Current data do not support a one-step disinfectant claim.
- f. Delete the "Safety" heading on the Technical Bulletin. Use a heading that reflects the concerns indicated in the paragraph about surface safety. Also precede the statements "Do not use, pour, spill . . ." with the Physical Hazards heading.
2. Submit the final printed labeling (label and technical bulletin) for inclusion in the product file.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

It should be understood that labeling for the various sizes of containers must be in compliance with the labeling bearing the acceptance stamp. However, the different container size labels should not be submitted for our review.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-1842.

Sincerely yours,



Jeff Kumpter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosure



GENERAL DESCRIPTION:

GSC liquid, germicidal synthetic, disinfectant/cleaner will clean and disinfect areas and equipment usually found in hospitals, nursing homes, and other places requiring a disinfectant/cleaner. It is a concentrated, multi-phenolic broad spectrum, germicidal liquid detergent; germicidal activity includes *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*, at 1 oz. per gallon (1:128) in 24 grain water.

PROPERTIES:

Appearance (as is) Clear amber liquid
Appearance (at use dilution):
Opalescent - typical of germicidal solutions.
Odor Mild nonphenolic
Foam Moderate
Rinsing Complete
Wetting Immediate
EPA Registration Number 5736-24

GERMICIDAL TESTS:

Microbiological Data: Official A.O.A.C. Methods, 13th Edition, 1960 Use Dilution Confirmation Test results, 24 grain water at 1:128, 1984

Pseudomonas aeruginosa (AATCC No. 15442) (PRD-10)
Staphylococcus aureus (ATCC No. 6538)
Salmonella choleraesuis (ATCC No. 1078)
Microbiological Data: Official A.O.A.C. Methods, 13th Edition, 1960 Use Dilution Confirmation Test results at 1:128.
Staphylococcus aureus (ATCC No. 6538)
Salmonella choleraesuis (ATCC No. 10708)
Pseudomonas aeruginosa (PRD-10)

Alcaligenes sp (ATCC No. 10153)
Diplococcus pneumoniae Type 1
Escherichia coli (ATCC No. 11229)
Klebsiella pneumoniae (ATCC No. 8045)
Lactobacillus leichmanii (ATCC No. 7830)
Neisseria catarrhalis
Proteus vulgaris (ATCC No. 9920)
Pasteurella multocida (ATCC No. 6535)
Salmonella schottmuelleri
Salmonella typhimurium
Serratia marcescens (ATCC No. 9986)
Shigella paratyphosiae Flexneri
Shigella sonnei
Streptococcus amolyticus (ATCC No. 7796)
Candida albicans (yeast)
Saccharomyces cerevisiae (yeast)

FUNGICIDAL (PATHOGENIC) ACTIVITY:

Trichophyton interdigitale (ATCC No. 9533) 1:128

TUBERCULOCIDAL ACTIVITY:

Mycobacterium tuberculosis var. *Bovis* BCG 1:100

In use areas such as shower room floors, locker room benches, both mats, or pre-cleaned, hard, inanimate surfaces.

DIRECTIONS FOR USE

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

For General Cleaning: GSC is to be used for cleaning surfaces such as floors and walls at a concentration varying from 1:30 to 1:128 depending on soil conditions.

For Disinfection: Recommended for use on pre-cleaned, hard, nonporous, inanimate surfaces. Apply GSC at a concentration of 1:128. Allow a 10 minute contact time and follow by a water rinse.

For Disinfection in Hospitals and Nursing Homes:

Thoroughly clean surface to remove heavy soil or gross filth prior to disinfecting. Apply GSC at a concentration of 1:128 for disinfecting surfaces such as floors, walls,

storage areas, metal furniture, cabinets, carts and other hard, nonporous, inanimate surfaces against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*. Allow a 10 minute contact time and follow by a water rinse. AOAC Use-Dilution Confirmation Method, 14th Edition, 1984.

For Laboratory Glassware and Surgical Instruments: Use GSC germicidal synthetic cleaner at 1:128 for presoaking before hand washing or machine washing to soften blood and soils. To disinfect after cleaning, soak glassware and surgical instruments for 10 minutes in a fresh solution.

For Rest Rooms and Locker Rooms: Use one ounce of GSC germicidal synthetic cleaner per gallon of water for cleaning and disinfecting floors, walls, lockers, fixtures and other hard surfaces in public rest rooms, gymnasiums, and locker rooms. Effective sanitation will reduce typical odors.

For Tuberculocidal Disinfection: Thoroughly pre-clean surface to remove heavy soil or gross filth before disinfecting. Use GSC Germicidal Synthetic Cleaner at 1:180. Allow a contact time of 10 minutes at 20°C. on hard, nonporous, inanimate surfaces and follow with a water rinse.

For fungicidal activity against *Trichophyton interdigitale* (pathogenic fungi) use GSC Germicidal Synthetic Cleaner at 1:128 (1 oz./gallon) on areas such as shower room floors, locker room benches, both mats or pre-cleaned, hard, inanimate surfaces.

STORAGE:

If frozen, thaw and mix to make usable.

SAFETY:

Solutions of GSC germicidal synthetic cleaner will not damage composition floors, painted surfaces, or metal furniture.

Use solution is conductive.

Do not use, pour, spill or store near heat or open flame. If frozen, thaw and mix to make usable. Do not mix with soap or other cleaning materials.

KEEP OUT OF REACH OF CHILDREN.

DANGER: Corrosive. Causes eye damage and severe skin irritation. Do not get in eyes, on skin, or on clothing. May be fatal or harmful if swallowed. Particular care should be taken in handling the concentrate, including proper shielding of eyes to prevent splashing. Use gloves for manual cleaning operations. Rinse empty container thoroughly with water and destroy or send to waste. No for use or storage in or around the home environment. Rinse with water anything that will come into contact with a baby's mouth. Do not use on surfaces that will come in prolonged contact with the skin.

FIRST AID: 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. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water, 100% alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsions may be needed.

PACKAGING:

Packed in 4 1 gallon (3.785 liters) plastic containers per case. Net weight 34 pounds; gross weight 37 pounds. 6 gal pail (22.7 liters); Net weight 50 pounds, gross weight 53 pounds. 55 gallon drums (208.2 liters); Net weight 463 pounds gross weight.

INC.

ACCEPTED
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5736-24

DUBOIS CHEMICALS