

011525-00030-050198

Printed: 10:46:44 Friday, 28 May, 1999 # 72 / 3192

Systems Integration Group, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAY 0 1 1998

April 21, 1998

CCL Manufacturing, Inc. c/o RegWest Company P.O. Box 2220 Greeley, CO 80632-2220

Attention: Kim Davis

Subject: Spray Disinfectant "G"

EPA Registration Number 11525-30

Your Submission Dated November 24, 1997 EPA Received Date November 25, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise labeling and an alternate formulation (three fragrances), is acceptable provided that you make the following labeling revisions:

- 1. In the statement, "Contains no CFCs or other ozone depleting substances", change "other ozone depleting..." to "other known ozone depleting...".
- 2. Revise the phrase, "Tuberculocidal in 10 minutes" to read, "Tuberculocidal in 10 minutes at 20 degrees Celsius."
- 3. On the middle of the front panel, the phrase "kills germs" is unacceptable and must be revised to read "kills most germs" or "kills many germs".
- 4. On the front panel, revise "bacteria" to read "kills many bacteria," and revise the term, "Viruses" to "kills most germs" or "kills many germs."
- 5. On the top of the back panel, delete the word "powerful."
- 6. Also, revise "advanced formula" to read "An effective formula"; and on the front panel, revise "This advanced Formulation" to read "This effective formulation."

7. On the back panel, revise "...on most environmental surfaces..." to read "on hard, nonporous environmental surfaces...".

CHEMISTRY

The alternate Confidential Statement of Formula dated November 24, 1997, for Disinfectant Spray "G" complies with PR Notice 95-2 and concurs with the label. The alternate Confidential Statement of Formula is acceptable.

EFFICACY

The submitted microbiological data developed by the AOAC Germicidal Spray Tests Method for the alternate formulations support the product's effectiveness as a disinfectant for precleaned, hard, nonporous surfaces for a ten minute exposure time against <u>Ps.aeruginosa</u>, <u>S.choeraeuis</u>, and <u>S.aureus</u>.

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

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely yours,

Marshall Swindell Product Manager (33)

Regulatory Management Branch I Antimicrobial Division (7510W)

DISINFECTANT SPRAY "G"

For Use in Homes, Offices, Institutions, Hospitals and Food Processing Plants

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 0 1 1998

Under the Federal Inceptionle, Pungicide, and Rodendelide Series amended, for the persolate, registered under EPA Reg. No.

11525-30

Eliminates Odors
Kills Many Household Germs
Kills Many Germs
Prevents Mold and Mildew Growth

Keep Out of Reach of Children WARNING

See side [back] panel for additional precautionary statements.

NET WT. __ OZ.

[Side Panels or Back Panel]

DIRECTIONS FOR USE

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

Remove gross filth and heavy soil deposits. Thoroughly clean surfaces or objects prior to application of product. Safe for use on surfaces and fabrics except polished wood, rayon fabrics or acrylic plastics.

To Disinfect: Spray 6 to 10 inches from clean surface for 3-4 seconds or until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surfaces for a minimum of 10 minutes prior to wiping. Tuberculocidal in 10 minutes.

For Herpes Simplex Type 2: Spray 6 to 10 inches from clean surface for 3-4 seconds or until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surfaces for a minimum of 10 minutes prior to wiping.

For Mildew: Clean surface, if necessary. Spray surface until thoroughly wet. Repeat weekly.

Product is restricted for use on clean, hard, non-porous surfaces in inedible product processing areas, non-processing areas and/or exterior areas. This product must not result in the direct or indirect contamination of food products. Do not use to mask odors resulting from unsanitary conditions.

DISINFECTS • VIRUCIDAL* • FUNGICIDAL • STREPTOCIDAL STAPHYLOCIDAL • TUBERCULOCIDAL • PSEUDOMONACIDAL

Fresh [or other descriptive term] Scent • Kills Germs, Bacteria and Viruses • Kills Germs Kills Salmonella choleraesuis (Salmonella), Staphylococcus aureus (Staph), Streptococcus pyogenes (Strep) and more!

Graphic Graphic Graphic

For the entire house

With all the news about germs and bacteria, just looking clean isn't good enough. Disinfectant Spray "G" kills household germs throughout the entire house plus prevents mold and mildew growth. This advanced formulation doesn't just mask odors, it eliminates them at their source, leaving behind a light fresh for other descriptive term] scent.

For use on hard non-porous surfaces in homes, offices, hospitals, institutions and food processing plants. Use on diaper changing tables, toys, plastic shower curtains, counter tops, chairs, desks, work benches, filing cabinets, wastebaskets, and in bathrooms, damp storage areas, closets and locker room facilities. Use in patient rooms, emergency rooms, operating rooms and recovery rooms. Effective on dressing carts, laundry chutes and patient care items.

For your entire household. For use on hard, non-porous surfaces in homes. Kitchens: sinks, drain boards, cabinets, counter tops, stoves, microwaves, refrigerators, garbage cans and under sinks; Bathrooms: basins, tubs, showers, toilets, toilet seats, hampers, tiled walls and trash cans; General Use: telephones, pet areas, diaper pails, chairs, desks, filing cabinets, door knobs and faucet handles.

Powerful formula eliminates odors at their source. Does not just mask odors. Kills household germs such as "Staph" and "Strep" as well as athlete's foot fungus on environmental surfaces. Inhibits mold and mildew growth on hard, nonporous surfaces.

Disinfectant Spray "G" can be used as a herpicidal toilet spray. When used as directed, this formula kills Herpes Simplex Type 2 on hard inanimate surfaces and toilet seats.

Advanced formula disinfects against all of the following organisms on most environmental surfaces [kills household getms: and bacteria such as:]

Staphylococcus aureus (Staph), Streptococcus pyogenes (Strep), Salmonella choleraesuis (Salmonella), Shigella dysenteriae, Mycobacterium smegmatis, Escherichia coli (E. coli), Pseudomonas aeruginosa, Salmonella typhimurium, Trichophyton mentagrophytes (Athlete's foot fungus), Aspergillus niger, Mycobacterium tuberculosis, *Influenza A2 virus, Salmonella shottmuelleri, Penicilum glacum, *Herpes Simplex Type 2. This formula is also tuberculocidal.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly ato 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.

STORAGE AND DISPOSAL

Storage: Store at temperatures below 120°F. Keep away from heat or open flame. Disposal: Replace cap and discard container in trash. Do not incinerate or puncture.

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ACTIVE INGREDIENTS:

C_{14} , 30% C_{16} , 3% C_{12} , 3% C_{18}) dimetryl benzyl	
ammonium chloride	0.072%
n-alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	0.072%
Ethanol	53.088%
INERT INGREDIENTS	46.768%
Contains sodium nitrite Total	100.000%

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

WARNING: Causes eye irritation. Do not get in eyes. In case of contact, flush eyes with water for 15 minutes and call a physician.

Physical or Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

Made by CCL Custom Manufacturing, Inc. Danville, IL 61832

EPA Reg. No. 11525-30

EPA Est. 11525-IL-1; 10744-IL-1; 11525-RI-1

Contains no CFCs or other ozone depleting substances Federal Regulations Prohibit CFC Propellants in Aerosols

Questions? Comments? (phone graphic)
Call toll-free 1-800-XXX-XXXX

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 0 1 1998

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

11525-30