

Claire Manufacturing Company
c/o Reg West Company
P.O. Box 2220
Greeley, CO 80632-2220

OCT 07 1999

Subject: Claire Disinfectant Bathroom Cleaner
EPA Registration No. 706-65
Application Date: 7/12/99
EPA Receive Date: 7/13/99

Attention: Ms. Kim Davis,
Consultant

The application referenced above, submitted in connection with registration under FIFRA, as amended, to update your label will be acceptable provided you address the following label recommendations before you release the product for shipment.

1. The phrase, "Kills Most Germs," is unacceptable. The Agency contends that the use of the terms "most germs" is too broad. You will need to revise the phrase by either qualifying the germs as "common household/kitchen germs" or by naming the specific bacteria this product mitigates with the phrase, "Kill the following bacteria." You should refer to the attached Agency letter dated 5/25/99 to the Chemical Specialties & Manufacturing Association on this issue.
2. The claims, "Staphylococidal and Pseudomonicidal," are unacceptable. This is a specific public health claim that says this product eliminates all *Staphylococcus* and *Pseudomonas* species, yet the submitted efficacy data demonstrates this product's effectiveness against *Staphylococcus aureus* and *Pseudomonas aeruginosa* only. You would need to submit data to support the Staphylococidal and Pseudomonicidal claims.

In regard to your contention that the Staphylococidal and Pseudomonicidal claims are similar to insecticidal and fungicidal claims, the Agency disagrees. Staphylococidal and Pseudomonicidal are specific public health claims regarding a specific genus's of bacteria whereas insecticidal and fungicidal are broad terms reflecting a class of organisms. You would be able to claim, Antibacterial, but not Staphylococidal or Pseudomonicidal.

3. Since this product is used in restaurants, you will need to include the following statement under "To Disinfect" in the "Directions/Instructions":

SYMBOL							
SURNAME							
DATE							

“When used as a disinfectant on food contact surfaces such as counter tops, tables, and appliances, wash surfaces thoroughly with a potable water rinse. Do not use on utensils, dishes, or glasses.

4. Since this product is used in hospitals, nursing homes, medical facilities on non-specific hard, non-porous environmental surfaces which could include but are not limited to bed frames, bed pans, ex-rays, stethoscopes, surfaces of a hemodialysis machine, or wheelchairs, the following MOU in PR Notice 94-4 will need to be added to the label preferably before the disinfection directions.

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..

5. After reviewing the submitted Data Matrix, you did not indicate how your product's formulation is supported by product chemistry data. When you originally submitted this application in December 21, 1998, you were adding organisms to the label which requires that Data Compensation be addressed. When you address the data compensation issue, you are required to submit a complete data matrix form that lists all the data submitted to support this product's registration (addressing all the data requirements) as well as the certification with respect to data citation form. You will need to cite the MRID Nos. for product chemistry data that was submitted to support this product's registration. If you are a Me-Too product, you will need to cite the registered product's chemistry data. (Please Note: Refer to the attached Agency letter dated 5/25/99 to the Chemical Specialties & Manufacturing Association on this issue.)

A stamped copy of the label is enclosed for your records. You should submit one (1) copy of the final printed label prior to the release of the product for shipment as well as submitting a revised data matrix that includes the product chemistry data. 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)

CLAIRE DISINFECTANT BATHROOM CLEANER



Disinfects

HIV-1 (AIDS Virus), Influenza A₂/Japan Virus
and Herpes Simplex Virus Types 1 and 2

On Hard Inanimate Nonporous Environmental Surfaces

For Use in Homes and Other Residential Dwellings,
Hospitals, Nursing Homes, Clinics, Medical Facilities, Businesses,
Hotels, Motels, Restaurants, Schools, Institutions and Commercial Establishments

Kills Most Germs

Bactericidal Staphylocidal
Pseudomonocidal *Virucidal
Fungicidal

Cleans and Deodorizes

Spray and Wipe Shining Clean

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT - 7 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 706-65

ACTIVE INGREDIENTS:

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.115%
n-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈)	
dimethyl ethylbenzyl ammonium chloride	0.115%
INERT INGREDIENTS	99.770%
Total	100.000%

Keep Out of Reach of Children
CAUTION
See back panel for additional precautionary statements.

EPA Reg. No. 706-65 EPA Est. 706-IL-1

NET WT. ____ OZ. (____ GRAMS)

Needs No Rinsing

Kills: *Candida albicans, Escherichia coli, Klebsiella pneumoniae, Penicillium pinophilum, Penicillium variable, Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus, Streptococcus pyogenes, Trichophyton mentagrophytes, Vancomycin-resistant Enterococcus faecalis, *Adenovirus Type 2, *Human Immunodeficiency Virus Type 1 [HIV-1 (AIDS Virus)], *Herpes Simplex Virus Types 1 and 2, *Influenza A₂/Japan Virus and Vaccinia (Poxvirus) on hard inanimate nonporous environmental surfaces.*

Disinfects: Acts as a disinfectant on hard, non-porous environmental surfaces such as toilet seats, fixtures, glazed tile, wash bowls, shower stalls, walls, finished woodwork and countertops.

The easy way to clean, disinfect and deodorize. Spray and wipe clean. Cleans and disinfects without scouring or scratching. Use in nursery and sickroom, for garbage and diaper pails, for any washable hard, non-porous environmental surface that needs disinfecting as you clean.

DIRECTIONS FOR USE

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

To Clean and Deodorize: Remove all gross filth or heavy soil from surfaces to be treated prior to using this product. **Shake Well Before Each Use.** Point valve opening toward area to be cleaned, press down firmly and spray evenly. Wipe clean with a dry cloth, turning frequently.

To Disinfect: After surface is cleaned, hold can upright 6" to 8" from surface to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping.

HIV on Pre-Cleaned Environmental Surfaces 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) (associated with AIDS): **Special Instructions for Cleaning and Decontamination Against HIV on Surfaces/Objects Soiled with Blood/Body Fluids: Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Spray surface to be treated 3-4 seconds, from a distance of 6-8 inches, until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Storage: Store in a cool, dry place (preferably locked) inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition. **Disposal:** Replace cap, wrap container in several layers of newspaper and dispose in trash collection. Do not incinerate or puncture.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

IRITATION: Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Statement of Practical Treatment

If Inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. **Get medical attention.** **If on Skin:** Wash with plenty of soap and water. Get medical attention if irritation persists. **If in Eyes:** Flush with plenty of water. Call a physician if irritation persists.

24 HOUR MEDICAL EMERGENCY: 1-800-228-5635, EXT. 009

Physical or Chemical Hazards

Contents under pressure. Do not use or store near fire, sparks or heated surfaces. Do not store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F (49°C) may cause bursting. Incineration of container may cause explosion.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT - 7 1999

A Product of



CLAIRE MANUFACTURING COMPANY

500 Vista Avenue
Addison, IL 60101

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 706-65