

4000-42
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 25 1995

Ms. Linda Kirk Kirby
Carroll Company
2900 West Kingsley Road
Garland, TX 75041

Dear Ms. Kirby:

Subject: Hospital Disinfectant
EPA Registration No. 4000-42
Your Resubmission Dated July 18, 1995

This is in response to your resubmission of revised labeling for the subject product.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable provided that you make the following revisions before you release the product for shipment bearing the amended labeling.

1. Revise the label ingredient statement as follows to reflect the nominal concentration in compliance with PR Notice 91-2.

Active Ingredients:

Isopropanol 69.52%
Ortho-Phenylphenol 0.16%
Inert Ingredients 30.32%

2. Change "nitrate" to "nitrite" below the ingredient statement.
3. Delete the Environmental Hazards section. This is only required for manufacturing use and outdoor use products.

A stamped copy is enclosed for your records.

Submit one copy of the final printed label for our records before you release the product for shipment bearing the amended labeling.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

If you have any questions, please call Marianne Clark at
(703) 305-7879.

Sincerely yours,



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

DIRECTIONS FOR USE (continued)

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 or high level disinfection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING: FLAMMABLE. KEEP OUT OF REACH OF CHILDREN. Harmful if swallowed. Avoid breathing spray mist. Avoid contact with eyes and skin. Avoid contamination of food and feedstuff. Remove pets, birds and cover fish aquariums before spraying.

STATEMENT OF PRACTICAL TREATMENT FIRST AID PROCEDURES

EYES: Flush with water 15 minutes. Seek medical attention. **SKIN:** Wash with soap and water. Seek medical treatment if irritation persists. **INGESTION:** Do not induce vomiting. Seek medical aid immediately.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and wildlife. Keep out of lakes, streams and ponds.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE: Contents under pressure. Do not use near fire, sparks or flame. Do not puncture or incinerate container. Exposure to temperatures above 120° F. may cause bursting. Do not use on polished wood furniture or rayon fabrics.

STORAGE AND DISPOSAL

STORAGE: Do not store in direct sunlight. Do not store above 120°F.

CONTAINER DISPOSAL: Do not reuse empty container. This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label. **DO NOT PUNCTURE!** If recycling is not available, wrap the container and discard in the trash. **DO NOT INCINERATE OR PUNCTURE!**

CAR885-0795

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This powerful hospital disinfectant and deodorant acts quickly and effectively to disinfect against many disease causing organisms on such germ laden surfaces as: refuse cans, toilet seats, door knobs, metal beds, wheel chairs, and office equipment when used as an mister spray following the proper cleaning of the surface. It reduces the hazard of cross contamination by bacteria via environmental surfaces. It is a nonselective, odor suppressant which chemically neutralizes odor producing materials. Effective on hospital, nursing home and other odors from many sources such as surgical dressings, post-colostomy and post-ileostomy dressings and bags, malignant diseases, bathrooms, kitchens, food processing plants, garbage cans and ericks damage. Destroys mildew on painted wood, metal, tile or other hard surfaces on contact.

Effective against the following organisms when used as a disinfectant on environmental surfaces: Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis, Herpes simplex Type 2, Influenza A2 (Asian Flu), Human immunodeficiency virus Type 1 (HIV-1).

***KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS 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-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PERSONAL PROTECTION: Cleanup should always be done wearing protective latex gloves, gowns, masks, and eye protection. **CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

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. **CONTACT TIME:** Surfaces must remain wet for 10 minutes.

DISINFECTING: Hold dispenser upright about 6" to 8" from surface to be disinfected and spray 3 seconds until surface is wet. Allow to remain 10 minutes before wiping. **DEODORIZING:** Hold dispenser upright—point opening away from face, spray into air towards center of room for about 4 seconds.

MILDEW CONTROL: Clean surface. Spray surface until wet, allow to air dry without wiping. Repeat application every week to maintain control.

FOOD PREPARATION AREAS: Remove all food and food processing surfaces or protect by covering before treating area. All treated food contact surfaces must be scrubbed thoroughly with detergent and rinsed with potable water before reuse.

HOSPITAL DISINFECTANT-DEODORANT

**TUBERCULOCIDAL · STAPHYLOCIDAL
BACTERICIDAL · FUNGICIDAL · VIRUCIDAL***

*Herpes simplex Type 2, Influenza A2 (Asian Flu)
Human Immunodeficiency virus, Type 1 (HIV-1)

ACTIVE INGREDIENTS:

Isopropanol 67.50%
Ortho-Phenylphenol 0.15%

INERT INGREDIENTS: 32.35%

Contains Sodium Nitrate

EPA Reg. No. 4000-42

EPA Est. 4313-TX-1

**WARNING: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
Harmful if Swallowed**

See right panel for additional precautions and first aid.

NET WT 14 oz (396 gm)

CARROLL

COMPANY

2900 W. KINGSLEY ROAD • GARLAND, TX 75041
214-278-1304 • FAX 214-840-0678 • 1-800-527-5722

ATLANTA (Macon)

DALLAS (Garland)

LOS ANGELES (Coyote)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 25 1995

Under the Federal Insecticide,
Fungicide and Rodenticide Act
and under the FIFRA pesticide
registered under EPA Reg. No. 4000-42

BEST COPY AVAILABLE