



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 2 7 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Linda Campbell Carroll Company 2900 W. Kingsley Road Garland, TX 75041

Subject:

776 Disinfectant Virucide & Cleaner

EPA Registration Number 4313-22 Application Dated August 1, 2008

Dear Ms. Campbell:

The following amendment submitted in connection with registration the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

Response to the Agency letter dated 5-29-08

General Comment:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter please contact Drusilla Copeland at (703) 308-6224 or Velma Noble (70) 308-6233

Sincerely

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Keep Out of Reach of Children. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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

(5 gallons and larger)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

776 DISINFECTANT, VIRUCIDE* & CLEANER

FOR HOSPITAL, INSTITUTIONAL AND INDUSTRIAL USE

*Human immunodeficiency virus, Type 1 (HIV-1)

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE LEFT/SIDE/RIGHT/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 4313-22 EPA Est. No. (as indicated on container) Net Contents (as indicated on container)

> Carroll Company 2900 West Kingsley Road Garland, TX 75041

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ACCEPTED

OCT 2 7 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 443/3-22

776 DISINFECTANT, VIRUCIDE* & CLEANER EPA Reg. No. 4313-22 EPA Draft 08.01. 2008 This disinfectant has a pleasing lemon fragrance and makes a bright, clear yellow solution when mixed with water. Do not mix with soap or other detergents.

DIRECTIONS FOR USE

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

For use on precleaned, hard, inanimate surfaces. For heavy soil or organic matter, a precleaning step is required. Rinse with clear water. Apply disinfectant solution of two ounces per gallon of water with cloth or mop to toilets, restroom floors, shower stalls, diaper pails and garbage cans. Wet all surfaces thoroughly. Use four ounces per gallon of water for sick rooms, hospitals, or clinics. Keep surfaces wet for at least 10 minutes. Prepare a fresh solution daily or when use solution becomes visibly dirty.

This product is effective against the following organisms:

Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis

Human immunodeficiency virus, Type 1

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. **DISINFECTION FOR TOILET BOWLS:** Flush toilet and add 2 ounces of disinfectant solution directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Keep surfaces wet for 10 minutes and flush.

*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** 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: Effective against HIV-1 (AIDS Virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when diluted 1:32. Surfaces must remain wet for 10 minutes at room temperature (20-25°C).

776 DISINFECTANT, VIRUCIDE* & CLEANER EPA Reg. No. 4313-22 EPA Draft 08.01, 2008 (Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap and discard in trash or recycle.

(Note to reviewer: If container is greater then one gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in areas inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal

(Plastic containers :)

Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Metal Containers :)

Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures approved by state and local authorities

776 DISINFECTANT, VIRUCIDE* & CLEANER EPA Reg. No. 4313-22 EPA Draft 08.01. 2008