11/28/2006 70369-7 UNITED STATES ENVIRONMENTAL PROTECTION AGENC

NOV 2 8 2006

Ms. Christina Swick Agent for Chemlink Laboratories, LLC Lewis and Harrison 122 C Street, NW Ste. 740 Washington, DC 20001

Subject:

RayCide

EPA Registration No.: 70369-2 Amendment Date: July 11, 2006 EPA Receipt Date: July 12, 2006

Dear Ms. Swick,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

Addition of organism, directions, and marketing claims

Acceptable Data

Data Requirement	Means of Support	Status		
AOAC Fungicidal Activity- T. mentagrophytes	Submitted study, MRID 468874-01	Acceptable, 1 tablet per 32 oz. of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Virucidal Efficacy of Disinfectant HIV-1	Submitted study, MRID 468874-02	Acceptable, I tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Virucidal Efficacy of Disinfectant Herpes Simplex Type I	Submitted study, MRID 468874-03	Acceptable, 1 tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 ininutes		
Virueidal Efficacy of Disinfectant Herpes Simplex Type 2	Submitted study, MRID 468874-04	Acceptable, I tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Virucidal Efficacy of Disinfectant Duck Hepatitis B Virus (surrogate for HBV)	Submitted study, MRID 468874-05	Acceptable, 1 tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Confirmatory Virueidal Efficacy - Duck Hepatitis B Virus (surrogate for HBV)	Submitted study. MRID 468874-06	Acceptable, 1 tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Virucidal Efficacy of Disinfectant Bovine Viral Diarrhea Virus (surrogate for HCV)	Submitted study, MRID 468874-07	Acceptable, I tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		
Confirmatory Viral Efficacy of Disinfectant - Bovine Viral Diarrhea Virus (surrogate for HCV)	Submitted study, MRID 468874-08	Acceptable, I tablet per 32 oz of water (2100 ppm) in 400 ppm hard water for 15 minutes		

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UNITED STATES ENVIRONMENTAL PAGECTION AGENCY

Conditions

Revise the label as follows:

1) Since this product is known to be corrosive. You must add the following guidance under "Salon (Barber) Instruments and Tools Directions:

Please Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

2) Under the HIV-1, HBV, and HBV directions, revise the Contact Time to read "15 minutes" as supported by the submitted data.

General Comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact Jacqueline McFarlane at (703) 308-6198.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

	Enclosure:	Stamped Lab	el				 ·
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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield or safety glasses. Wear protective clothing and gloves. Wash thoroughly with soap and water after handling, before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

(Note to Reviewer: Boxed format or bullets may be used in First Aid Section if label space permits.)

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. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

[If container size is 5 lbs or less, add the following statement:] STORAGE AND DISPOSAL

Store this product in a cool, dry area away from direct sunlight and heat and in an area inaccessible to children. Do not reuse empty packet. Wrap packet and place in normal trash.

[If container size is greater than 5 lbs add the following statement:] STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat in an area inaccessible to children.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these

wastes cannot be disposed of by use according to tabel Inder the Federal Interction, instructions, contact your State Pesticide or Environmental Americade, and Rodenticide Act as Control Agency, or the Hazardous Waste representative attandade, for the pesticide, the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty packet. Wrap packet and place in normal trash.

RayCide

DISINFECTANT

FOR USE IN SPAS, BEAUTY SALONS, BARBERSHOPS, AND HAIR STYLING FACILITIES

Effective against Staphylococcus aureus, Salmonella cholaraesuis, Staphylocidal,

SalmonelicidalTrichophyton mentagrophytes, Herpes Simplex Type 1, Herpes Simplex Type 2, HIV-1 (AIDS Virus), Hepatitis B Virus (HBV) & Hepatitis C Virus (HCV)

KEEP OUT OF REACH OF CHILDREN

DANGER

See [left] [right] [side] [back] [top] [other] panel for Precautionary Statements and First Aid

EPA Reg. No. 70369-2
EPA Est. No. (as indicated on container)
Net Contents:
Tablet: 30g
Four (4) Tablets per [Container][Box]

[Manufactured by:] [For Exclusive Distribution by:] Chemlink Laboratories LLC, Kennesaw, GA 30144

RayCide EPA Reg. No. 70369-2 Label Updated 7/11/06 (Note to reviewer: Language in [] is optional or interchangeable)

DIRECTIONS FOR USE

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

RayCide tablets are recommended for use on brushes, combs, rollers, manicure and other tools used in spas, beauty salons, barbershops, and hair styling facilities. RayCide tablets are effective for immersion and the disinfection of inanimate, non-porous surfaces. Drop one 30 gram tablet into [32 fl. oz.][1 liter] of warm water (2100 ppm active).

Salon (Barber) Instruments and Tools Disinfection: Thoroughly clean and rinse instruments before disinfection. Completely immerse combs, brushes, roller, razors, scissors, blades, manicure and other salon instruments and tools for 15 minutes at room temperature. Then remove, rinse thoroughly, and dry before reuse. Fresh solution must be prepared daily or more often if solution becomes visibly diluted or soiled.

General Disinfection: Thoroughly pre-clean surfaces. Apply use solution with mop, sponge, or cloth, thoroughly wetting hard nonporous surfaces. Treated surfaces must remain wet for 15 minutes. Allow to air dry or wipe dry with cloth, sponge, or mop. Prepare a fresh solution daily or more often if the use solution becomes visibly soiled or diluted.

[PERFORMANCE: When tested with full immersion for 15 minutes in a solution prepared [as above] [in accordance with the directions for use], RayCide tablets have been found to be effective against Staphylococcus aureus, Salmonella choleraesuis, Trichophyton mentagrophytes, Herpes simplex Type 1 and Type 2, Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus), Hepatitis B Virus and Hepatitis C Virus.]

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS), HBV OR & HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/ AND BODY FLUIDS in health care settings or other set-tings in which there is an expected likely-hood 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), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

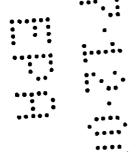
PERSONAL PROTECTION: When handling items solled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

CONTACT TIME: Leave surface wet for 10 minutes.

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.

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RayCide EPA Reg. No. 70369-2 Label Updated 7/11/06 (Note to reviewer: Language in [] is optional or interchangeable)