

70369-2

07/14/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 23 2005

Anna-Rodriguez-Koster
Lewis and Harrison LLC
Agent for Chemlink Laboratories, Inc.
122 C Street N.W., Suite 740
Washington D.C. 20001

Subject: EPA Reg. No.70369-2
Application Dated: June 20, 2005
Receipt Date: June 22, 2005

Dear Ms. Tannehill,

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification

- Addition of marketing language
- Addition of small self-sealed envelopes.
- Correction of typographical error

Comments

Based on a review of the material submitted, the following comments apply: The application for notification to add the marketing language, small self-sealed envelopes, and to correct a typographical error is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

CONCURRENCES

SYMBOL	75100						
SURNAME	N. S.						
DATE	07-14-05						

Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division (75100)

LEWIS & HARRISON

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

Consultants In Government Affairs
June 20, 2005

HAND DELIVERED

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTENTION: Velma Noble
Product Manager, Team 31

SUBJECT: ChemLink Laboratories, LLC
Raycide (EPA Reg. No. 70369-2)
Notification of Minor Label Changes per PR Notice 98-10

Dear Ms. Noble:

On behalf ChemLink Laboratories, LLC, we are submitting an application for pesticide Notification to propose some minor changes to the label for their product, **Raycide (EPA Reg. No. 70369-2)** in accordance with PR Notice 98-10. These changes include:

- a) Addition of marketing language to accommodate final market label layout and supplemental distributor information;
- b) Revision of a typographical error present in the use directions for the disinfection of Salon (Barber) instruments and Tools;
- c) Inclusion of a foil wrap label for individual tablets of **Raycide**. This label was inadvertently left out of the original submission package for **Raycide**. Please note that each **Raycide** tablet is individually packaged in a foil wrap container that is then placed inside an outer box container, which follows the most recent EPA stamped accepted language for **Raycide**. Tablets will **NOT** be sold individually. Furthermore, the language present in the foil wrap meets the guidelines provided by the most recent EPA Label Review Manual dated August 2003 (Chapter 18, Section III A & B).

Enclosed please find the following documents in support of this submission:

- 1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10;
- 2. One (1) copy of the proposed product labeling, with changes highlighted; and,
- 3. One (1) clean copy of the proposed product labeling.

Thank you for your assistance with this submission. If you have any questions, please call me at 202-393-3903 x.17 or e-mail me at alkoster@lewisharrison.com if you have any questions.

Sincerely,

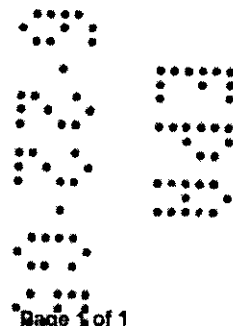


Ana Rodriguez-Koster
Agent for ChemLink Laboratories, LLC

Enclosures

cc: Ryan Moore, ChemLink Laboratories, LLC

Raycide (EPA Reg. No. 70369-2)
Notification of Minor Label Changes per PR Notice 98-10



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EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other: Notification	OPP Identifier Number 265394
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Application for Pesticide - Section I

1. Company/Product Number 70369-2	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ChemLink Laboratories, LLC	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) ChemLink Laboratories, LLC 1590 North Roberts Road NW, Suite 111 Kennesaw, GA 30144 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

NOTIFICATION OF ADDITIONAL MARKETING LANGUAGE AND FOIL LABEL PER PR NOTICE 98-10

Notification of ADDITIONAL Marketing Language and Individual Foil Package Label in Accordance With PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Ana Rodriguez-Koster Date: 6/20/05

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Metal <input type="checkbox"/> Plastic: <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section - IV

1 Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name: Ana Rodriguez-Koster, Lewis and Harrison, LLC 122 C St., NW Suite 740 Washington, DC 20001	Title: Agent for ChemLink Laboratories, LLC	Telephone No (Include Area Code): (202) 393-3903 ext. 17
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2 Signature 	3. Title: Agent for ChemLink Laboratories, LLC	
4. Typed Name Ana Rodriguez-Koster, Lewis & Harrison LLC	5. Date 6/20/2005	

**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 label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at 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

Staphylocidal, Salmonelicidal

Active Ingredients:

Alkyl (60% C ₁₄ ; 30% C ₁₆ ; 5% C ₁₂ ; 5% C ₁₈) dimethyl benzyl ammonium chlorides	3.625%
Alkyl (68% C ₁₂ ; 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	3.625%
Other Ingredients:.....	92.75%
Total	100.000%

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]

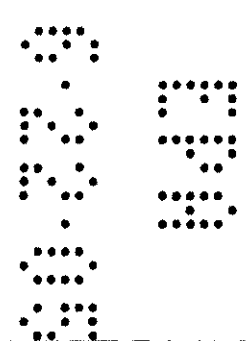
[Manufactured by:] [For Exclusive Distribution by:]
Chemlink Laboratories LLC, Kennesaw, GA 30144

RayCide

EPA Reg. No. 70369-2

Label Updated 6/20/05 - Notification to USEPA Submitted 6/20/05 Page 1 of 2

(Note to reviewer: Language in [] is optional or interchangeable)



DIRECTIONS FOR USE

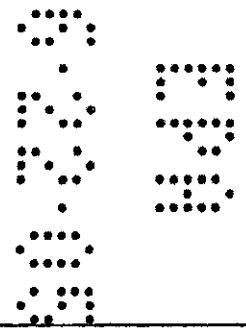
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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).

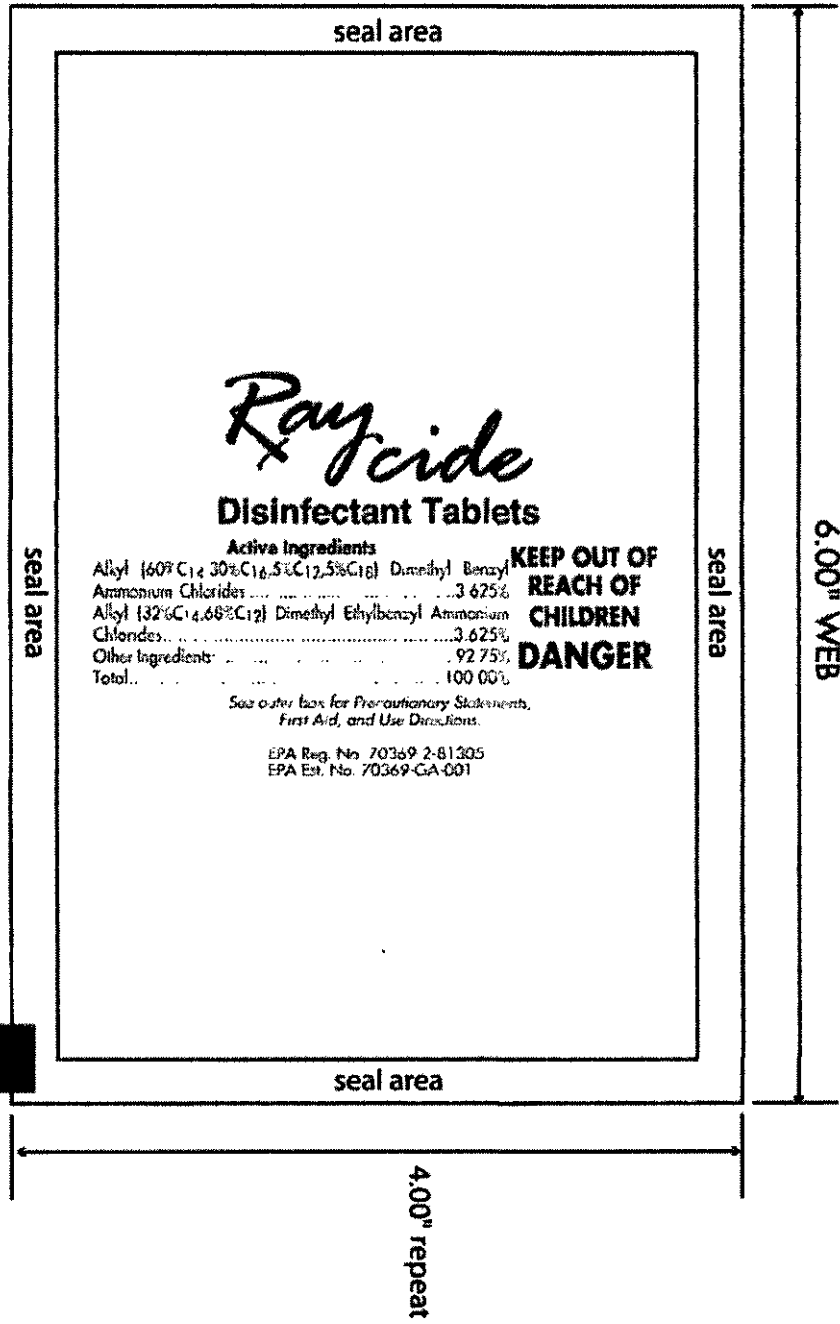
Salon (Barber) Instruments and Tools Disinfection: Thoroughly clean and rinse instruments before disinfection. Completely immerse combs, brushes, roller, razors, scissors, blades, manicure and other salon instruments and tools for 15 minutes at room temperature. Then remove, rinse thoroughly, and dry 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* and *Salmonella choleraesuis*.]



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