

84878-2

07-09-2009

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

July 9, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Amy Plato Roberts
Regulatory Consulting for
Citrefine International Ltd.
1150 18th Street, NW, Suite 1000
Washington, DC 20036

RE: Product Name: Citrepel
EPA Reg. No: 84878-2
Application for Label Notification Dated May 11, 2009 to Add Optional Label
Claims and an Alternate Brand Name: Citrapel

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Should you have any questions concerning this action, please feel free to contact Ms. Diana Hudson at (703) 308-8713 or email at HUDSON.DIANA@EPA.GOV.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 848782		2. EPA Product Manager Linda Hollis		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) CITREPEL		PM# 91/Biochemical Branch/BPPD			
5. Name and Address of Applicant (Include ZIP Code) Citrefine International Ltd. Moorfield Rd, Yeadon, Leeds England LS19 7BN <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

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

Date Reviewed: 7-9-09
 Reviewed By: D. Hudson

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

NOTIFICATION to add an alternate brand name and optional label claims.

This notification is consistent with the provisions of PR Notices 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 for 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 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <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
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 on container label

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Amy Plato Roberts / aroberts@tsgusa.com	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8964
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Certification

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.

2. Signature 	3. Title Regulatory Consultant	6. Date Application Received (Stamped)
4. Typed Name Amy Plato Roberts	5. Date May 11, 2009	



May 11, 2009

WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Linda Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: CITREPEL Insect Repellent; EPA Reg. No. 84878-2

NOTIFICATION of an alternate brand name and optional label claims

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Ms. Hollis:

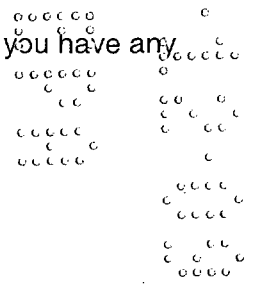
Enclosed with this letter you will find the following in support of a notification to add an alternate brand name and optional label claims to the above referenced product, EPA Reg. No. 84878-2:

- 1) Notification form; and
- 2) One (1) copy of the revised label all changes highlighted in redline.

Changes made via notification are:

- Addition of the alternate brand name: "Citrapel™".
- Addition of a website in the company name and address.
- Modification of the currently approved optional label claim "Repels mosquitoes that may transmit West Nile Virus" to read "Repels mosquitoes [including those] that may [transmit] [carry] West Nile Virus [for up to six hours]. This modified claim is consistent with already approved label claims.
- Addition of the optional label claims "DEET Free" and "Contains no DEET." Both claims are factual statements and have been previously approved in other similar non-DEET mosquito repellent products handled by BPPD (for example: BullFrog® Mosquito Coast® - EPA Reg. No. 40086-1; BullFrog® Mosquito Coast® Twilight – 40086-2).

There are no other changes made to the label at this time. If you have any questions or comments, please don't hesitate to contact me.



CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

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WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

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May 11, 2009

Sincerely,

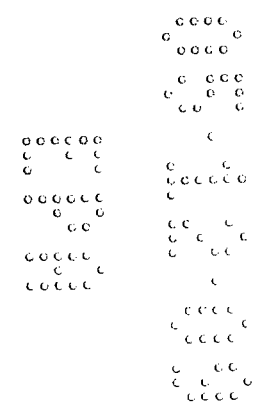
Amy Plato Roberts
Regulatory Consultant for Citrefine International Ltd.
Direct dial: (202) 828-8964; Email: aroberts@tsgusa.com

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754



NOTIFICATION

Date Reviewed: 7-9-09

Reviewed By: D. Hudson

Citrepel

[Insect Repellent]

Alternate Brand Name: Citrapel™

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautions and first aid statements

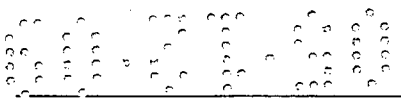
Active Ingredient:

Oil of Lemon Eucalyptus*	30.9%
Other Ingredients	69.1%
TOTAL	100.0%

*Approx. 65% p-menthane-3,8-diol

NET X fl oz (XXmL)

[Bracketed Text] = Optional language



OPTIONAL MARKETING LANGUAGE

[Citrepel insect repellent is designed to repel mosquitoes for up to six hours. This unique formula is guaranteed to repel mosquitoes. You can use Citrepel with confidence knowing that it will not harm your fishing line, camping gear, watch crystals or tackle box. Apply Citrepel and get your adventure started.]

You can use Citrepel [insect repellent] with confidence knowing it will not harm your fishing line, camping gear, watch crystals or tackle box. Apply Citrepel and get your adventure started. The active ingredient in Citrepel is derived from the leaves of the Lemon Eucalyptus tree.

STOP. READ ENTIRE LABEL BEFORE EACH USE.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Wash Hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. After returning from outdoors, wash product from all exposed skin. Do not allow children to apply this product to themselves. Do not apply to the hands of children. Do not use on children under the age of three years. May cause skin reactions for some people. Discontinue if irritation or rash appears. Do not apply over cuts, wounds or irritated skin.

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. 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 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. In case of emergency call 1-800-332-5553.

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Physical or Chemical Hazards

COMBUSTABLE. Keep away from heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

To repel insects, apply to exposed skin and clothing. For best results, spread evenly with hand to moisten all exposed skin. Do not spray directly on face. To apply to face, dispense on palm of hand and spread on face and neck. Reapply once as needed. Do not apply more than twice per day.

STORAGE AND DISPOSAL: Store the product in a cool, dry place, out of reach of children. If empty: Nonrefillable container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

[Questions or Comments?]

Made for Citrefine International Ltd
Moorfield Rd, Yeadon
Leeds, England LS19 7BN
(website)

EPA Reg. No. 84878-2

OPTIONAL MARKETING CLAIMS

- 1. Contains Lemon Eucalyptus Oil
- 2. Active Ingredient extract of Lemon Eucalyptus
- 3. Active Ingredient Derived from Plant Extracts

[Bracketed Text] = Optional language

- 4. Gives Mosquitoes the Brush-Off

- 5. Active Ingredient derived from plant extracts
- 6. Active Ingredient Derived from Lemon Eucalyptus
- 7. Contains plant extracts [of Lemon Eucalyptus]
- 8. Repels [annoying] mosquitoes
- 9. Delivers up to 6 hours of repellency of Mosquitoes
- 10. Repels up to 6 hours against mosquitoes
- 11. Repels mosquitoes for up to 6 hours
- 12. Won't harm your gear
- 13. Will not [melt][damage][weaken] your fishing line
- 14. Will not harm watch crystals, tackle boxes, backpacks, fishing line, tents or bedding.
- 15. Goes on easy
- 16. Lemon Eucalyptus scent
- 17. Cool, refreshing [lemon eucalyptus] scent
- 18. Botanically-based active ingredient
- 19. Plant-based active ingredient
- 20. Effective, Dependable mosquito repellency for up to six hours
- 21. Unique formula
- 22. Unique plant-based active ingredient
- 23. New formula [to be removed 6 months after first shipment]
- 24. [Contains](made with) Oil of Lemon Eucalyptus
- 25. Powered by Citriodiol® OLE Nature's Repellent (logo)
- 26. Naturally-based active ingredient
- 27. Active ingredient derived from [the leaves of] Lemon Eucalyptus tree
- 28. [By][From][Brought to you buy] the makers of Citirepel®
- 29. Not Sticky or greasy
- 30. Repels mosquitoes [including those] that may [transmit] [carry] West Nile Virus [for up to six hours]
- 31. Repels annoying mosquitoes
- 32. Cool Lemon Eucalyptus scent
- 33. DEET Free
- 34. Contains no DEET

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