

84878-1

7/9/2009

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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 Lotion
EPA Reg. No: 84878-1
Application for Label Notification Dated May 11, 2009 to Add Optional Label
Claims and an Alternate Brand Name: Citrapel Lotion Insect Repellent

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)

2007



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 84878-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CITREPEL LOTION	PM# 91/Biochemical Branch/BPPD	
5. Name and Address of Applicant (Include ZIP Code) Citrefine International Ltd. Moorfield Rd, Yeaton, 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**

Notification - Explain below. Other - Explain below. Date Reviewed: 7-9-09

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

Reviewed By: D. Hudson

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 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	

3097



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 LOTION Insect Repellent; EPA Reg. No. 84878-1

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. 84878-1:

- 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™ Lotion Insect Repellent".
- Addition of a website in the company name and address.
- Modification of the currently approved optional label claim "Effective protection against the mosquitoes that may carry the West Nile Virus" to read [Effective] [protection] [Protects] against [the] mosquitoes that may carry [the] West Nile Virus". 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.

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WASHINGTON

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

Page 2 of 2
May 11, 2009

Sincerely,

A handwritten signature in black ink, appearing to read "Amy Plato Roberts". The signature is fluid and cursive, with a large, sweeping flourish extending to the right.

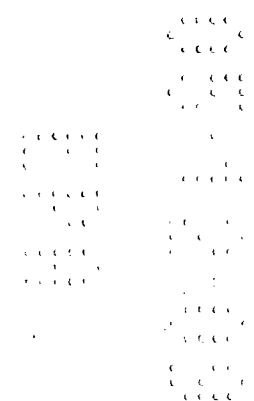
Amy Plato Roberts
Regulatory Consultant for Citrefine International Ltd.
Direct dial: (202) 828-8964; Email: aroberts@tsgusa.com

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

507

Date Reviewed: 7-9-09

Reviewed By: D. Hudson

Citrefine International Ltd
EPA Reg. No. 84878-1

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MASTER LABEL

Citrepel Lotion

Alternate Brand Name: Citrapel™ Lotion
Insect Repellent

Effective Repellent for the Whole Family

KEEP OUT OF REACH OF CHILDREN

WARNING:

See back panel for precautions and first aid statements.

ACTIVE INGREDIENTS:

Oil of Lemon Eucalyptus*.....30.0%

OTHER INGREDIENTS 70.0%

TOTAL100.0%

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

Net wt. X oz. (XX g)

Back Labeling

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.

(One of the following directions for use is required based on the formulation/type packaging.)

(1. Lotion/Cream formulation, ex. squeeze tube)

To repel insects, apply a smooth even layer on exposed skin areas. Reapply once as needed. Do not apply more than twice per day.

(2. Spray-able Lotion, example spritzer)

(SHAKE WELL BEFORE USE.) To repel insects spray on exposed skin, spread evenly with hands after application. Do not spray in enclosed areas. If used on the face, spray on palms of hands first and then apply sparingly, avoiding eyes and mouth. Do not spray directly onto face. (Use on clothing may cause discoloration.) Reapply once as needed. Do not apply more than twice per day.

STORAGE AND DISPOSAL: Store in a cool, dry place. If empty: Nonrefillable container. Do not reuse this 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.

Precautionary Statements:

Hazard to Humans and Domestic Animals

WARNING: Causes substantial but temporary eye injury. 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. Remove and wash contaminated clothing before reuse. 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.

Citrepel Lotion; EPA Reg. No. 84878-1
NOTIFICATION to add an alternate brand name and
optional label claims
MASTER LABEL version (2) dated May 9, 2009
p. 1 of 3

Citrefine International Ltd
EPA Reg. No.: 84878-1

p. 2 of 3

FIRST AID	
If in eyes	<p>If in eyes:</p> <ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).</p>	

Physical or Chemical Hazards: Combustible.
Do not use or store near heat or open flame

EPA Reg. No. 84878-1 EPA No.
Citrefine International Ltd
Moorfield Rd, Yeadon, Leeds, England LS19 7BN
(website)

(Questions or comments?)

MASTER LABEL

The following statements are optional marketing claims

- ❖ Citrepel (Lotion/Cream) (insect repellent) is made from a renewable resource.
- ❖ Insect Repellent for the (whole or entire) family
- ❖ Proven effective against mosquitoes (and deer ticks)
- ❖ Protection from annoying mosquitoes (and deer ticks)
- ❖ Repels mosquitoes (and deer ticks)
- ❖ Citrepel (Lotion/Cream) repels mosquitoes (and deer ticks) for up to six hours
- ❖ Oil of Lemon Eucalyptus is from a renewable source
- ❖ Derived from plant extracts
- ❖ Derived from Lemon Eucalyptus
- ❖ Derived from oil obtained from the leaves of the Eucalyptus tree
- ❖ Derived from the Eucalyptus tree
- ❖ Contains plant extracts (of Lemon Eucalyptus)
- ❖ Extracts of Lemon Eucalyptus
- ❖ Contains eucalyptus oil
- ❖ Outdoor protection
- ❖ Clean fresh scent
- ❖ Pleasant scent
- ❖ Not sticky or greasy
- ❖ Plant based (insect repellent)
- ❖ Lotion (cream) formula
- ❖ Gives Mosquitoes and Deer Ticks the Brush-Off
- ❖ Outwit Outplay Outlast The Australian Outback
- ❖ Eucalyptus citriodora tree
- ❖ Other ingredients consist of water, alcohol, emulsifiers and preservatives.
- ❖ Lotion (Spray or Pump) formulation
- ❖ (Spray-able or Pump) Lotion
- ❖ For easy application
- ❖ Provides a smooth even coverage.

- ❖ Insect Repellent (Spray) Lotion
- ❖ Effective Protection
- ❖ [Effective] [protection] [Protects] against [the] mosquitoes that may carry [the] West Nile Virus
- ❖ Protects against mosquitoes that may carry West Nile Virus
- ❖ Citrepel Works
- ❖ Citrepel Lotion Lemon Eucalyptus Insect Repellent is made from a renewable resource. It is plant-based and derived from oil obtained from the leaves of the Eucalyptus citriodora tree. Citrepel Lemon Eucalyptus gives you up to 6 hours of protection in a lotion that is not sticky or greasy.
- ❖ DEET Free
- ❖ Contains no DEET

Key
Italicized text is for informational purposes
 (Optional text) – May be left out of text, use in place of preceding text or in conjunction with preceding text.
 ❖ Optional text/information may or may not be on label

First Aid statements should be in a solid box or presented in an easy to use fashion.