

70051-13

04/01/2004

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
70051-13

2. EPA Product Manager /Branch Chief
Dr. Sheryl K. Reilly

3. Proposed Classification
☒ None ☐ Restricted

4. Company/Product (Name)
Neem Oil RTU

PM#

5. Name and Address of Applicant (Include ZIP Code)

Certis USA, L.L.C.
9145 Guilford Road, Suite 175
Columbia, Maryland 21046

☐ 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.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to
Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

NOTIFICATION

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

Notification to update homeowner disposal instructions per PR Notice 2001-6.

Notification of label change relative to PR Notice 2001-6. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of 40 CFR 156.10 and 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 guidance of PR Notice 2001-6 and the requirements of 40 CFR 156.10 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.

Date Reviewed: 4/1/04

Reviewed By: *CP/MSD*

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes
☒ No

Unit Packaging

☐ Yes
☒ No

Water Soluble Packaging

☐ Yes
☒ No

2. Type of Container

☐ Metal
☒ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

* Certification must
be submitted

If "Yes"
Unit Packaging wgt.

No. per
container

If "Yes"
Package wgt

No. per
container

Location of Net Contents Information

☒ Label ☐ Container

4. Size(s) Retail Container

1 qt., 24 oz

5. Location of Label Directions

☒ on package

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

Christine A. Dively

Title

Director of Regulatory Affairs

Telephone No. (include Area Code)

301-483-3806

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.

6. Date Application
Received
(Stamped)

2. Signature

Christine A. Dively

3. Title

Director of Regulatory Affairs

4. Typed Name

Christine A. Dively

5. Date

November 24, 2003



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Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046
(301) 604-7340
FAX (301) 604-7015
www.certisusa.com

November 24, 2003

Dr. Sheryl K. Reilly
Branch Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway, Crystal Mall 2
Arlington, VA 22202

**Re: Notification to Update Homeowner Disposal Instructions per PR Notice 2001-6 for
Neem Oil RTU, EPA Reg. No. 70051-13**

Dear Dr. Reilly:

On behalf of Certis USA, L.L.C. (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I am respectfully submitting the enclosed Notification to update the homeowner disposal instructions (per PR Notice 2001-6) on the label for Neem Oil RTU, EPA Reg. No. 70051-13. Enclosed in support of this action are:

- 1) Completed form 8570-1, Notification
- 2) One copy of the revised label with changes clearly marked

Please be advised that on 5/5/03, we submitted an amendment to the Agency to update the First Aid statement (per PR Notice 2001-1) and the homeowner disposal instructions (per PR Notice 2001-6) on this label. However, since this amendment is still in review at the Agency, we are submitting this notification so that we may begin using the revised disposal instructions on the Neem Oil RTU label. Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively

Christine A. Dively
Director of Regulatory Affairs

Enclosures

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Certis USA, L.L.C.

NEEM OIL RTU

BROAD SPECTRUM BOTANICAL FUNGICIDE/INSECTICIDE/MITICIDE

Water-Based

For use on roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables in and around the home and home garden.

Controls blackspot, powdery mildew, rust, spider mites, aphids, whiteflies, and other insect pests.

ACTIVE INGREDIENT:

Clarified Hydrophobic Extract of Neem Oil 0.9%

INERT INGREDIENTS: 99.1%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See inside panels for additional precautionary statements.

Manufactured by:

CERTIS

Certis USA, L.L.C.
9145 Guilford Rd. Suite 175
Columbia, Maryland 21046

EPA Reg. No. 70051-13

EPA Est. No. _____

Net Contents: _____

NOTIFICATION

Date Reviewed: 4/1/04

Reviewed By: C. Pellack

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. In case of contact, flush eyes or skin with plenty of water. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to wetlands. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters

BEE HAZARD

This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.

STORAGE & DISPOSAL

Pesticide Storage: Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Keep from freezing.

Disposal Instructions:

If empty: 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.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Keep unprotected persons out of treated areas until sprays have dried.

GENERAL INFORMATION

- Multi-purpose organic fungicide/insecticide/miticide-3 in 1 product.
- Kills eggs, larvae and adult stages of insects.
- Prevents fungal attack of plant tissues.
- Not for use in food-handling areas.
- Shake well before using
- Neem Oil RTU is most effective when applied in early to mid-morning or late afternoon when adult pests are normally sedentary on the undersides of foliage.
- Thorough plant coverage is essential to obtain optimal levels of control.
- Do not apply to wilted or otherwise stressed plants, or to newly transplanted material prior to root establishment.
- As with other pest control products, care should be exercised in timing applications to early morning/late evening to minimize the potential for leaf burn.
- Use with care on plants with tender tissue. Check for leaf burn in small-scale trials prior to use.

FUNGICIDE USE

Application Instructions

- Neem Oil RTU is an effective fungicide for the prevention and control of various fungal diseases including black spot on roses, powdery mildew, downy mildew, anthracnose, rust leaf spot, botrytis, needle rust, scab, and flower, twig and tip blight.

- Neem Oil RTU may be used on all roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables grown in and around the home and home garden.
- As a preventative, Neem Oil RTU should be applied on a 7 to 14 day schedule until the potential for disease development is no longer present. Spray to run off. Complete coverage of all plant tissue is necessary for control.
- To control disease already present, apply Neem Oil RTU on a 7-day schedule until disease pressure is eliminated. Then continue spraying on 14-day schedule to prevent the disease from recurring. Spray to run off. Complete coverage of all plant tissue is necessary for control.
- To prevent rust leaf spot diseases, anthracnose, and scab, begin applications at the first sign of spring budding.
- To prevent powdery mildew, apply in mid-summer or when disease is first detected. Applications should continue until disease pressure no longer exists.
- To prevent black spot on roses, applications should begin at first bud emergence in spring. Apply Neem Oil RTU on a 14-day preventative schedule through the spring and fall to prevent disease emergence.

INSECTICIDE USE

Application Instructions

- Neem Oil RTU is an effective insecticide for the control of various insects pests including whiteflies, mealy bugs, armyworms, hornworms, leafhoppers, bagworms, leafminers, psyllids, fruit flies, loopers, budworms, beetles (including Japanese beetles), aphids, scales, caterpillars, midges, budworms, and mites (including spider mites)
- Neem Oil RTU may be used on all roses, flowers, houseplants, ornamental trees and shrubs, fruits, nuts, and vegetables grown in and around the home and home garden.
- Apply Neem Oil RTU at first sign of insects/mites. Neem Oil RTU is most effective in controlling insects/mites when applied on a 7-14 day schedule. For heavy insect populations, apply on a 7-day schedule. Spray to run off. Complete coverage of all plant tissue is necessary for control.

EPA 080697

EPA 080697 disposal markup