

70051-6

07/23/2004

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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 70051-6	2. EPA Product Manager /Branch Chief Dr. Sheryl K. Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Meen	PM#	
5. Name and Address of Applicant (Include ZIP Code) Certis USA, L.L.C. 9145 Guilford Road, Suite 175 Columbia, Maryland 21046 <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.

NOTIFICATION
Date Reviewed: 7/23/04

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 EPA's regulations at 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 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.

Reviewed By: cpellard

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" 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
16oz, 8oz.

5. Location of Label Directions
 _____ on container

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

Section - IV

.. 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) 301-483-3805
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 <u>Christine A. Dively</u>	3. Title Director of Regulatory Affairs	
4. Typed Name Christine A. Dively	5. Date <u>November 24, 2003</u>	



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

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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

BPRD
[unclear]

Re: Notification to Update Homeowner Disposal Instructions per PR Notice 2001-6 for Meen, EPA Reg. No. 70051-6

Dear Dr. Reilly:

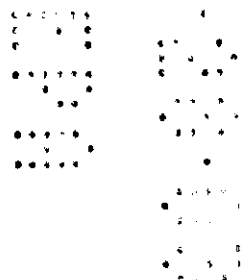
On behalf of Certis USA, L.L.C. (9145 Guilford Road, Suite 175, Columbia, Maryland 21046), I am respectfully submitting the enclosed Notification to update the homeowner disposal instructions (per PR Notice 2001-6) on the label for Meen, EPA Reg. No. 70051-6. Enclosed in support of this action are:

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

Please be advised that on 5/16/03, 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 Meen 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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MEEN
BOTANICAL INSECTICIDE CONCENTRATE
INSECT GROWTH REGULATOR
INSECT GROWTH INHIBITOR
INSECT REPELLENT
INSECT FEEDING INHIBITOR
ADULT INSECT REPRODUCTIVE INHIBITOR/DISRUPTOR

Kills or repels various [listed] insect pests [including...] on ornamentals, trees, lawns, shrubs, flowers, and vegetables in the yard and garden, and in and around interiorscapes and homes.

MEEN disrupts the molting ability of immature insects of many types, inhibits feeding, and acts to disrupt the reproductive capacity of many insect adults.

Active Ingredient:

Azadirachtin.....	0.09%
Inert Ingredients.....	<u>99.91%</u>
Total.....	100.0%

EPA Registration No: 70051-6

EPA Establishment No:

Keep Out of Reach of Children

CAUTION

See Back Panel for Additional Precautionary Statements

Net Contents:

MANUFACTURED BY:
 CERTIS USA, L.L.C.
 9145 GUILFORD ROAD
 SUITE 175
 COLUMBIA, MD 21046

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Caution: Harmful if swallowed. Avoid contact with skin, eyes, or clothing. Avoid contamination of feed and foodstuffs. Avoid breathing spray mist. In case of eye contact, flush eyes with plenty of water. If on skin, wash with soap and water. Wash contaminated clothes before reuse. If irritation persists, get medical attention.

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Environmental Hazards:

This product may be hazardous to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of water.

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

Storage and Disposal

Storage: Keep in original container. Store in a cool, dry place, away from direct sunlight, feed or foodstuffs. Keep container tightly sealed when not in use. Do not store below 50°F (10°C) or above 95°F (35°C).

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.

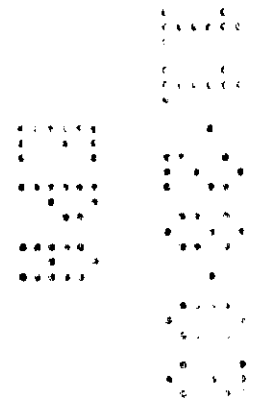
General

- Botanical Insecticide Concentrate
- Insecticide, Repellant, Insect Growth Regulator
- All-Purpose Insect Control
- All-Purpose Insecticide
- Broad Spectrum Insecticide
- Broad Spectrum Insect Control
- Broad Spectrum Organic Insecticide
- Organic Insect Control
- Organic Insecticide
- Organic Active Ingredient
- Insect Anti-Feedant
- Multi-Purpose Insecticide
- Multi-Purpose Organic Insecticide
- Kills and/or repels insects/Japanese beetles.
- Kills larval stages of insects.
- Organically kills insects
- Organically repels Japanese beetles.

NOTIFICATION

Date Reviewed: _____

Reviewed By: _____



- For Indoor and Outdoor Use
- Formulated for Interiorscape use.

General Information

MEEN's effectiveness is based on several modes of action. It disrupts insects' delicate hormonal balance so they die before they molt to the next life stage. MEEN suppresses some insects' desire to feed and also repels many insects in areas that have been sprayed. These different modes of action result in broad spectrum control of the majority of insects that harm your yard and garden.

[MEEN's effectiveness is based on three modes of action:

- 1. Anti-feedant: MEEN suppresses the insect's desire to feed and, therefore, no damage is caused.*
- 2. Repellant: Insects simply stay away from areas sprayed with MEEN and, therefore, no damage is caused.*
- 3. Insect Growth Regulator: MEEN disrupts the insect's delicate hormonal balance so it dies before it molts to the next life stage.]*

MEEN kills or repels a broad assortment of insect pests. MEEN spares many beneficial insects such as honey bees and lady bugs that prey on undesirable insects. Without beneficial insects to control pest populations, plants are even more vulnerable to new infestations.

Neem-based products have been extensively tested and used as effective insecticides in commercial greenhouses. The Neem seed has been the subject of extensive testing throughout the world *[since after WWII]*. Neem has been tested at major universities throughout the U.S. since 1982.

The active ingredient in MEEN is an organic. It comes from a natural source: an extract from the seeds of the neem tree, a renewable resource. Parts of the neem tree have been used over the centuries for highly effective insecticidal and medicinal purposes. The neem tree is native to India, Africa, and several other tropical countries. Over the years, people have stored their food grains, in the home, free from pest infestation by adding whole or chopped neem seeds. The trees are also planted in backyards and common areas in order to repel insects.

Shake well before using.

Spray solutions should be used within 8 hours of mixing for maximum effectiveness. Do not store diluted spray solution for later use.

Not for use in food handling areas.

Since MEEN interferes with insect growth function, it is most effective when applied 2-3 times at 7-10 day intervals.

Application directly onto the target pest will increase efficacy. Time applications for early to mid-morning or in the late afternoon.

Do not add other chemicals to MEEN solutions.

Do not apply to wilted, stressed, or newly transplanted materials prior to root development. Do not apply to known sensitive plant species without prior testing.

Known Sensitive Plants

Do not apply MEEN to the following plant species due to potential plant damage:

Hibiscus flowers

The Following Section Contains Directions For Concentrate Products Use

(1) Foliar Application (Bedding & Potted Plants)

For use on bedding plants, potted and foliage plants, ornamentals, trees and shrubs, in and around homes to control the immature or larval forms of the following insect pests:

PESTS

- Leafhoppers
- Leafminers
- Whiteflies
- Thrips
- Mealybugs
- Loopers
- Caterpillars
- Aphids
- Fruitflies
- Beet armyworms
- Mexican Bean Beetles

USE DIRECTIONS

Dilute MEEN to a concentration of 3 fl. Oz. (6 tablespoons) of MEEN per gallon of water (1 part MEEN to 40 parts water). Mix thoroughly. Apply with a hand sprayer as a fine spray to leaf surfaces to run-off. Be sure to coat undersides of leaves as this is where many insects hide. Excessive application is unnecessary and should be avoided.

(2) Foliar Application (Trees & Shrubs)

For use on trees and shrubs on residential landscapes to control the immature larval stages of the following insect pests:

PESTS

- Leafhoppers
- Leafminers
- Gypsy moths
- Weevils
- Psyllids
- Webworms
- Hornworms
- Spruce budworms
- Pine sawflies
- Elm leaf beetle
- Bagworms
- Tent Caterpillars
- Grasshoppers

USE DIRECTIONS

Dilute MEEN to a concentration of 3 fl. Oz. (6 tablespoons) of MEEN per gallon of water (1 part MEEN to 40 parts water). Mix thoroughly. Apply with a hand sprayer as a fine spray to leaf surfaces to run-off. Be sure to coat undersides of leaves as this is where many insects hide. Excessive application is unnecessary and should be avoided.

(3) Lawn Application

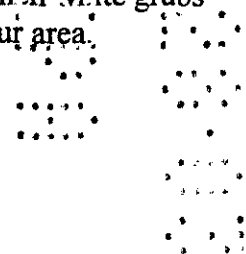
For home lawns to control the following insect pests:

PESTS

- Mole crickets
- White grubs
- Sod webworms
- Fall armyworms
- Chinch bugs
- Hyperodes weevils
- Billbugs
- Crane flies

USE DIRECTIONS

Dilute 2 fl. Oz. (4 tablespoons) of MEEN in 1 gallon of water. Apply at the rate of 5 gallons spray solution per 2000 square feet. Apply MEEN at least 3 times on a 7-10 day interval to insure effective control of surface and sub-surface feeding pests. MEEN should not be applied to newly seeded lawns. Best timing for initial white grub application will vary by region but is generally early to mid summer and again in the fall. If in doubt, contact your local university research or extension specialist for the periods when white grubs are feeding in your area.



(4) Yard and Landscape MEEN Concentrate

For use around the home to control the following insects:

PESTS

- Aphids
- Caterpillars
- Gypsy moth larvae
- Immature tent beetles
- Webworms
- Bagworms
- Lace bugs
- Box elder bugs
- Leafhoppers
- Psyllids
- Sawfly larvae
- Woolly aphids

USE DIRECTIONS

Always use freshly mixed spray solution. Use soft water whenever possible. Use with caution on new tender foliage, and do not apply to plants in direct sunlight. When insects are first noticed, apply a mixture of 3 fl. Oz. (6 tablespoons) of MEEN per gallon of water (1 part MEEN to 40 parts water). Repeat applications 2-3 times on a 7-day interval. Heavy infestations may require more frequent applications on a 3-4 day interval until populations are reduced.

(5) House Plant Application

For use on house plants to kill or repel the following insect pests:

PESTS

- Leafhoppers
- Leafminers
- Whiteflies
- Thrips
- Mealybugs
- Loopers
- Caterpillars
- Aphids
- Fruitflies
- Beet armyworms
- Mexican bean beetles
- Fungus gnats

USE DIRECTIONS

Dilute MEEN to a concentration of 0.42 fl. Oz. (2 1/2 teaspoons) of MEEN per pint of water. Mix thoroughly. Adjust spray bottle nozzle to spray setting and apply MEEN to leaf surfaces until completely wet. Be sure to coat undersides of leaves especially those at the soil surface as this is where many insects hide. Excessive application is unnecessary and should be avoided.

(6) Vegetable and Fruit Crop Application

For use on vegetable and fruit crops to kill or repel the following insect pests:

PESTS

- Armyworms
- Diamondback moths
- Hornworms
- Imported cabbageworms
- Loopers
- Melonworms
- Pickleworms
- Tomato fruitworms
- Corn earworms
- Bollworms
- Budworms
- Whiteflies
- Thrips
- Borers
- Aphids
- Squash bugs
- Tent caterpillars
- Mexican bean beetles
- Pinworms
- Colorado potato beetles
- European corn borers
- Cucumber beetles
- Leafminers

- Vine borers
- Cutworms
- Weevils
- Bean leaf beetles
- Leafrollers
- Grape leaf skeletonizers
- Twig girdlers
- Codling moths

USE DIRECTIONS

Always use freshly mixed spray solution. Use soft water whenever possible. Use with caution on new tender foliage. When insects are first noticed, apply a mixture of 3 fl. Oz. (6 tablespoons) of MEEN per gallon of water (1 part MEEN to 40 parts water). Repeat applications 2-3 times on a 7-day interval. Heavy infestations may require more frequent applications on a 3-4 day interval until populations are reduced.

CROPS

- Broccoli
- Turnips
- Cabbage
- Tomatoes
- Melons
- Kale
- Mustard
- Peppers
- Lentils
- Squash
- Lettuce
- Beans
- Corn

- Potatoes
- Peanuts
- Asparagus
- Garlic
- Parsley
- Radishes
- Rutabaga
- Anise
- Mint
- Dill
- Rosemary
- Sweet bay
- Thyme
- Almonds
- Pecans

Pistachios
 Apples
 Pumpkins
 Peaches
 Plums
 Figs
 Lemons
 Cauliflower
 Celery
 Kohlrabi
 Carrots
 Spinach
 Turnip greens
 Brussels sprouts
 Sweet potatoes
 Cucumbers
 Collards
 Beets
 Peas
 Eggplants
 Ginger

Artichokes
 Onions
 Turnips
 Bok choy
 Collard greens
 Mustard greens
 Basil
 Chives
 Marjoram
 Sage
 Tarragon
 Wintergreen
 Cashews
 Macadamia nuts
 Walnuts
 Cherries
 Cantaloupes
 Pears
 Apricots
 Oranges
 Limes

The Following Section Contains Directions for Use of the product in a Hose-End Applicator

(7) Foliar Application (Bedding and Potted Plants): For use on bedding plants, potted and foliage plants, ornamentals in and around homes to control the immature or larval forms of the following insect pests:

PESTS

Leafhoppers
 Leafminers
 Whiteflies
 Thrips
 Mealybugs
 Loopers
 Caterpillars
 Beet armyworms
 Aphids

The 16 oz. hose end applicator for bedding and potted plants will treat approximately 650 square feet of plant material 3 times. Repeat application 2 to 3 times at an interval of 7-10 days. Apply to leaf surfaces to run-off. Be sure to coat undersides of leaves as this is where many insects hide. Excessive application is unnecessary and should be avoided. Do not apply to known sensitive plants without a prior small scale test application.

1. Remove plastic wrap from carton and detach hose-end attachment.
2. Screw the longer end of the hose-end attachment onto hose.
3. Set valve switch to off position (at right angle to line of water flow).
4. Remove child resistant cap from product bottle and screw bottle top onto hose-end attachment until tight.
5. Turn faucet on. Begin spraying by turning the valve switch located on top of the attachment clockwise until fully in line with water flow.
6. When spraying is complete, turn valve switch counter clockwise to stop product flow.
7. Turn off faucet.
8. Unscrew product bottle from hose-end attachment, recap bottle and if empty dispose of according to label directions. Unscrew hose-end attachment from hose.

(8) Foliar Application (Trees and Shrubs)

For use on trees and shrubs on home landscapes to control the immature larval stages of the following insect pests:

PESTS

- Leafminers
- Leafhoppers
- Gypsy moths
- Weevils
- Psyllids
- Webworms
- Hornworms
- Spruce budworms
- Pine sawflies
- Elm leaf beetle
- Grasshoppers

USE DIRECTIONS

The 16 oz. hose end applicator for trees and shrubs will treat up to 5 ten foot trees. Repeat application 2 to 3 times at an interval of 7-10 days. Apply to leaf surfaces to run-off. Be sure to coat undersides of leaves as this is where many insects hide. Excessive application is unnecessary and should be avoided.

1. Remove plastic wrap from carton and detach hose-end attachment.
2. Screw the longer end of the hose-end attachment onto hose.
3. Set valve switch to off position (at right angle to line of water flow).
4. Remove child resistant cap from product bottle and screw bottle top onto hose-end attachment until tight.
5. Turn faucet on. Begin spraying by turning the valve switch located on top of the attachment clockwise until fully in line with water flow.

- 6. When spraying is complete, turn valve switch counter clockwise to stop product flow.
- 7. Turn off faucet.
- 8. Unscrew product bottle from hose-end attachment, recap bottle and if empty dispose of according to label directions. Unscrew hose-end attachment from hose.

(9) **Lawn Application:** For use on home lawns to control the immature larval stages of the following insect pests:

PESTS

- Mole crickets
- White grubs
- Sod webworms
- Fall armyworms
- Chinch bugs
- Hyperodes weevil
- Billbugs

USE DIRECTIONS

The 16 oz. hose-end applicator for lawns will treat approximately 1,000-2,000 square feet. *[The 32 oz. hose-end applicator for lawns will treat approximately 2,000-4,000 square feet.]* Apply MEEN at least 3 times on a 7-10 day interval to insure effective control of surface and sub-surface feeding pests.

- 1. Remove plastic wrap from carton and detach hose-end attachment.
- 2. Screw the longer end of the hose-end attachment onto hose.
- 3. Set valve switch to off position (at right angle to line of water flow).
- 4. Remove child resistant cap from product bottle and screw bottle top onto hose-end attachment until tight.
- 5. Turn faucet on. Begin spraying by turning the valve switch located on top of the attachment clockwise until fully in line with water flow.
- 6. When spraying is complete, turn valve switch counter clockwise to stop product flow.
- 7. Turn off faucet.
- 8. Unscrew product bottle from hose-end attachment, recap bottle and if empty dispose of according to label directions. Unscrew hose-end attachment from hose.

10) Hose-end Sprayer Refill ^(a)

- 1. Remove child resistant cap from product bottle and screw bottle top onto hose-end attachment until tight.
- 2. Turn faucet on. Begin spraying by turning the valve switch located on top of the attachment clockwise until fully in line with water flow.
- 3. When spraying is complete, turn valve switch counter clockwise to stop product flow.
- 4. Turn off faucet.
- 5. Unscrew product bottle from hose-end attachment, recap bottle and if empty dispose of according to label directions. Unscrew hose-end attachment from hose.

(a) Will also contain appropriate application directions as per the foregoing.

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The Following Section Contains Directions For Use Of The Product As A Repellant

Repellency Against Japanese Beetles and Other Pests:

MEEN repels a variety of pests including armyworms, aphids, and Japanese Beetles. Apply to plants at labeled rate, being sure to completely cover foliage and flowers. Apply just before pests emerge or at first sign of infestation. Repeat applications every 3-7 days or immediately after significant rainfall.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.**

M042594 disposal markup

