

84185-4

4/19/2011

1/12



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Olav Messerschmidt
Registration Agent,
Plasma Power Private Ltd
c/o OMC Ag Consulting
828 Tanglewood Lane
East Lansing, MS 48823

APR 19 2011

Subject: Notification to Add ⁰¹¹Non-Public Health Pest per PRN 98-10
Product Name: Plasma Neem Biological Insecticide
EPA Reg. No: 84185-4
Your Submission Dated March 7, 2011

Dear Mr. Messerschmidt,

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10, as referenced above. A screen of this request has been conducted for applicability under PRN 98-10, and it has been determined that the action request falls within the scope of this document. Our records have been duly noted, and the product label submitted with this application has been stamped "Notification Accepted" and will be placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Casciano at (703) 605-0513 or via email at casciano.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. 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 Plasma Power Private Limited/ 84185 - 4		2. EPA Product Manager Linda Hollis		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Plasma Neem Oil - Biological Insecticide		PM# 91			
5. Name and Address of Applicant (Include ZIP Code) Plasma Power Private Limited 123 New Avadi Road Kilpauk, Chennai 600 010, India <input checked="" type="checkbox"/> Check if this is a new address			6. Expedited Review Notification Accepted (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u> </u> Date: <u>4/19/11</u> Product Name <u> </u> Reviewer: <u>G. Casciano</u>		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <u> </u>
<input type="checkbox"/> Resubmission in response to Agency letter dated <u> </u>	<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.)

Additional pest added to label: root knot nematode

Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
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		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u> </u>	
* 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container 1Qt to 55 gallons		5. Location of Label Directions <input checked="" type="checkbox"/>		
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled				<input type="checkbox"/> Other <u> </u>			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Olav Messerschmidt		Title Registration Agent		Telephone No. (Include Area Code) 587-881-0100	
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 			3. Title Registration Agent		
4. Typed Name Olav Messerschmidt			5. Date March 7, 2011		

9/1 3/12
OMC Ag Consulting

March 7, 2011

Ms. Linda Hollis
Biochemical Pesticides Branch Chief (PM #91)
Document Processing Desk (DPD) (**NOTIF**)
Biopesticides & Pollution Prevention Division (BPPD) – 7504P
U. S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460-0001

Subject: Plasma Neem Oil Biological Insecticide (84185-4)
Labeling Notification – new pest added

Dear Ms. Hollis:

In support of this Notification, attached are the following documents:

- Application for Pesticide Registration (EPA Form 8570-1)
- One copy of the label with all proposed changes highlighted
- 5 copies of the draft label

This Notification adds a new pest, the root knot nematode, to the subject label. Per PR Notice 98-10, the addition of new pests is allowed as long as the new pest is not a public health pest and the use sites do not change; both conditions are met.

Please note that the company's address has changed. EPA's Kathleen O'Malley has been formally notified of the address change.

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 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.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 or by email at omesserschmidt@comcast.net

Sincerely,




Olav Messerschmidt,
Registration Agent for Plasma Power Private Limited

4/12

Plasma Neem[®] Oil (azadirachtin 3000 ppm) BIOLOGICAL INSECTICIDE

Anti-Feedant, Insect Repellent, Insect Growth Regulator

*For Non-Crop and Crop Uses
including vegetables, fruits, nuts, and ornamental plants*

 FOR ORGANIC PRODUCTION
[OMRI Seal]

Notification Accepted

Date: 4/19/11

Reviewer: G. Casciano

Active Ingredient:

Cold Pressed Neem Oil*	100.0%
Other Ingredients	<u>0.0%</u>
Total	100.0%

* Contains 0.02503 lb. azadirachtin per gallon (azadirachtin 3000 ppm)

KEEP OUT OF REACH OF CHILDREN CAUTION

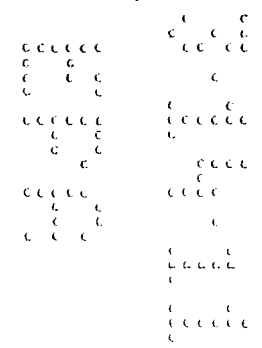
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

If you do not understand the label, find someone to explain it to you in detail (Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.)

NET CONTENTS 1 Quart to 55 GALLONS

EPA Reg. No. 84185 - 4
EPA Est. No. 84185 - IND - 1

Manufactured by:
Plasma Power Private Limited
123 New Avadi Road
Kilpauk, Chennai 600 010, India
Tel: +91-44-26224503 / 26260485
Fax: 1-800-859-7115 (Toll free) / +91-44-26268609
Email: manager@plasmaneem.com
Website: <http://www.plasmaneem.com>



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Route of Entry	First Aid
If inhaled	Move the person to fresh air. If person is not breathing, call 911 or an ambulance and then give artificial respiration, preferably mouth-to-mouth if possible. Call a doctor or poison control center for treatment advice.
If on skin or clothing	Remove contaminated clothing. Rinse skin immediately with plenty of water for about 15 minutes. Call a doctor or poison control center for treatment advice.
If in eyes	Hold eye open and rinse slowly and gently with water for about 15 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eyes. Call a doctor or poison control center for treatment advice.
If swallowed	Call a poison control center or doctor immediately for treatment. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless instructed to do so by a poison control center or doctor.
<p align="center">Have the product container or label with you when calling a poison control center or doctor or going for treatment. FOR MEDICAL EMERGENCIES INVOLVING THIS PRODUCT, CALL TOLL FREE 1-800-859-7115</p>	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long sleeved shirt and long pants
- Chemical resistant gloves
- Shoes with socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions are available, wash with detergent and hot water. Keep and store PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. When handlers use closed systems, enclosed cabs or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40CFR170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS. **IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water bodies. Do not contaminate water when cleaning equipment or disposing wash water. 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 when disposing of equipment washwater or rinsate

USER SAFETY RECOMMENDATIONS

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if contaminated with pesticide. Wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during product application. For any requirements specific to your state or tribe, consult the state or tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical resistant gloves
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

These requirements apply to uses of this product that are NOT within the scope of the WPS for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses. For other uses, including golf courses and other non-agricultural uses, do not enter treated areas without protective clothing until sprays have dried

PRODUCT MODE OF ACTION

Plasma Neem® Oil (azadirachtin 3000 ppm) controls target pests primarily by ingestion and also by contact. The modes of action are repellence, anti-feeding action and interference with the molting process.

GENERAL INFORMATION

Read all directions before using this product.

Apply **Plasma Neem® Oil (azadirachtin 3000 ppm)** as directed to any food or non-food crop up to and including the day of harvest, at a maximum rate of 3½ pints **Plasma Neem® Oil** /acre (emulsified by using at least 11 fl. oz. of surfactant plus 40 gallons of water). In most cases, use a concentration of 0.5% **Plasma Neem® Oil** in water plus surfactant. In case of severe infestation or for aerial application, use a 1.1% concentration. Do not use a concentration above 1.1% **Plasma Neem® Oil**. Refer to the Mixing and Application Instructions for mixing and rate instructions, and to Use Site Section for a complete listing of crops.

MIXING

Plasma Neem® Oil (azadirachtin 3000 ppm) is pure neem oil and requires a surfactant, such as soap, dish washing fluid, or emulsifier such as soap nut for dilution with water.

Note: Plasma Neem® Oil must be diluted with water and a surfactant in order to form a spray able emulsion.

- Use a concentration of 0.5% (1 part of Plasma Neem® Oil to approximately 200 parts of water).
- In cases of severe infestation or for aerial spraying applications, the concentration of Plasma Neem® Oil can be increased to 1.1% (1.1 parts of Plasma Neem® Oil to approximately 100 parts of water). Do not use a concentration above 1.1% Plasma Neem Oil.
- Do not attempt application without adding adequate quantity of surfactant as improper emulsification will result in phyto toxicity.

Add the surfactant, such as soap, and **Plasma Neem® Oil (azadirachtin 3000 ppm)** to a mixing tank, and stir. The ratio of surfactant to **Plasma Neem® Oil (azadirachtin 3000 ppm)** must be in the ratio 1:5. For every pint of **Plasma Neem® Oil (azadirachtin 3000 ppm)**, use at least 3 fl. oz. of surfactant. Then add water to the spray tank with continuous agitation. Use warm water if ambient temperature is below 60° F.

Applying the product immediately after preparation assures that it is in suspension. To prevent separation of the emulsion, mix thoroughly and continue agitation while spraying. Non-uniform mixing can cause crop injury or result in lowered effectiveness. For tank mixtures add components to the tank containing the Plasma Neem® Oil (azadirachtin 3000 ppm) spray mixture and agitate thoroughly. If tank mixture is allowed to sit, agitation is necessary prior to application. Adjusting the spray mixture pH between 5.5 and 7 will provide optimal performance. Always use this product promptly after mixing with water and do not let tank mix sit for any extended period.

COMPATIBILITY: Along with the recommended quantity of surfactant or emulsifier, **Plasma Neem® Oil (azadirachtin 3000 ppm)** is best applied independently but has been found to be compatible with tank mixes including liquid fertilizers such a fish emulsion and adjuvants like karanja oil, cottonseed oil, sesame oil and castor oil. Always read and follow the directions for use, precautions and limitations for use on all product labels used in combination. Applications must follow the precautions and limitations of the most restrictive product label in the mixture. Do not exceed the dosage rates of any product. Check compatibility by using the correct proportion of the products in a small test container. Test the tank-mix combinations for possible adverse effects (such as settling out, flocculation, etc.) and for phyto toxic effects on a small sample of plants prior to use. As environmental conditions can alter the interactions between compounds, in order to test for compatibility a test shall be conducted for both new and previously used combinations. Avoid mixtures of several materials and very concentrated spray mixtures. Do not use if this oil does not form a uniform, milky emulsion. Adjust with addition of warm water or more emulsifier and agitate before use.

Plasma Neem® Oil (azadirachtin 3000 ppm) may not be compatible with deltamethrin formulations such as Decis®.

PHYTOTOXICITY: When used according to label instructions, **Plasma Neem® Oil (azadirachtin 3000 ppm)** has been evaluated for phytotoxicity on a wide range of crops and ornamentals. However, it is recommended that testing of a small portion of the area to be treated for phyto toxicity be conducted before treating the entire area. Further, all possible mixtures of pesticide sprays, other fertilizers, surfactants, adjuvants, have not been tested. Therefore testing for phyto toxicity of spray mixtures is recommended. Spray equipment used to apply **Plasma Neem® Oil (azadirachtin 3000 ppm)** must be thoroughly cleaned before use. Tank mix combinations of **Plasma Neem® Oil (azadirachtin 3000 ppm)** may be incompatible with oil-based formulations.

APPLICATION INSTRUCTIONS

Spray when the onset of pests (see Pest List) is expected or soon after pests are noticed. When used as a foliar application, spray **Plasma Neem® Oil (azadirachtin 3000 ppm)** in a suitable high volume sprayer with adequate spray pressure to ensure complete and thorough coverage of the plant surfaces. Ensure that both the top and bottom of leaves are wetted. For optimum results, repeat the applications at intervals of 7-10 days. Use higher rates and increase spray frequency when pest pressure is high. Spray early in the morning or in the evening for best results. Repeat application if it rain within four hours of spraying.

SPRAY DIRECTIONS

Apply **Plasma Neem® Oil (azadirachtin 3000 ppm)** as a foliar spray or as soil drench to control insects. When needed, soil drenches can also be used to control soil borne pests and larvae of pests. When applied as a soil drench, avoid excessive run off. **Plasma Neem® Oil (azadirachtin 3000 ppm)** can also be applied through sub-surface soil treatment equipment. Always follow equipment manufacturer's use directions. **Plasma Neem® Oil (azadirachtin 3000 ppm)** may be applied using any powered or manual pesticide application equipment which includes high volume, low volume, ultra-low volume, electrostatic and fogging. Follow the original manufacturer's instructions when using these types of equipment.

RATES

For most pest and crop conditions, use **Plasma Neem® Oil (azadirachtin 3000 ppm)** at 1-2 pints/acre using a 0.5% concentration of **Plasma Neem® Oil (azadirachtin 3000 ppm)** in water. Use at least 3 – 6 ½ fl. oz. of surfactant for emulsification.

(1 pint of **Plasma Neem® Oil** + 3 fl. oz of surfactant + 25 gallons of water)

(2 pints of **Plasma Neem® Oil** + 6 1/2 fl. oz. of surfactant + 50 gallons of water)

In the case of very heavy pest pressure, use up to 3½ pints per acre in a 1.1% concentration of **Plasma Neem® Oil (azadirachtin 3000 ppm)** in water. Use at least 11 fl. oz. of surfactant for emulsification.

(3 ½ pints of **Plasma Neem® Oil** + 11 fl. oz. of surfactant + 40 gallons of water)

When used alone (without fertilizers or other pesticides) for sensitive crops such as lettuce, spinach and asparagus, use 6 fluid ounces per acre of **Plasma Neem® Oil (azadirachtin 3000 ppm)** in a 0.5% concentration of **Plasma Neem® Oil (azadirachtin 3000 ppm)** in water. Use 1 fl. oz. of surfactant for emulsification. The amount of **Plasma Neem® Oil (azadirachtin 3000 ppm)** may be reduced by 50% when tank mixed with other compatible products.

USE SITES

CROP USES – Use **Plasma Neem® Oil (azadirachtin 3000 ppm)** on the following crops:

Alfalfa, Beans, Berries, Bulb Vegetables, Cereal Grains, Citrus fruits, Cole Crops, Cotton, Cucurbits, Fruits, Herbs, Legumes, Leafy and Fruiting Vegetables, Peanuts, Roots and Tubers, Pome and Stone Fruits, Tree Nuts and Tropical Fruits.

NON-CROP USES – Use **Plasma Neem® Oil (azadirachtin 3000 ppm)** on non-crop use sites including: ornamentals, nurseries, and fencerows

PESTS

Plasma Neem® Oil (azadirachtin 3000 ppm) may be used against the following pests:

Aphids: (Cotton aphids, Cowpea aphids, Mustard aphids, Okra aphids, Pea aphids, Rice aphids).

Beetles: Brinjal (Egg Plant) Spotted Leaf Beetle, Chick pea beetle, Cow pea beetle, Colorado potato beetle, Cucumber beetle, Mexican Bean beetle, Radish Flea beetle, Red Pumpkin beetle, Spotted cucumber beetle, Soya bean Japanese beetle).

Stink bugs: Tomato stink bugs

Caterpillars: Black headed caterpillar, Cabbage caterpillar, Ear cutting caterpillar, Tobacco caterpillar, Yellow hairy caterpillar

Leafhoppers: Brown plant hopper, Carolina grass hopper, Leaf hopper, Potato leaf hopper, Rice brown plant hopper, Rice grass hopper, Rice green leaf hoppers

Leafminers: Leafminers of ornamental plants, tomato leaf miner.

Whiteflies: Cotton white fly, Sugar cane white fly, Banded wing white flies, citrus white flies

Mealy Bugs: Mealy bugs of ornamental plants

Midges: Brassica pod midge

Mites: Spider Mites

Nematodes: Root knot nematodes

Weevils: Black Vine Weevil

Scales: California red scales, Yellow scales, Coffee green scales

Thrips: PeanutThrips

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by pesticide storage or disposal.

PESTICIDE STORAGE: Do not store this product above 104°F or below 20°F for extended periods of time. Keep containers tightly closed and in original containers when not in use. Do not store exposed to ultraviolet light (sunlight) or moisture. Neem oil clouds and solidifies at temperatures below 59°F. If oil has solidified, gently thaw by exposing to temperatures over 80°F. Store in such a manner to prevent cross contamination with other pesticides, fertilizers, food and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Keep container closed when not in use.

PESTICIDAL DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

5-Gallon or Smaller Containers: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Containers Larger than 5 Gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

NOTICE ON CONDITIONS OF SALE

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Seller. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Seller makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Seller is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Seller disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Seller election, the replacement of product.

Plasma Neem® Oil (azadirachtin 3000 ppm) is the registered trademark of Plasma Power Private Limited. Contains Plasma Neem® Oil manufactured by Plasma Power Private Limited, India.