

070191-1

4-11-2003

1/15

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-3



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 070191-00001	2. EPA Product Manager Debbie McCall	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Organica(R) K+NEEM Insecticidal Soap Concentrate	PM#	
5. Name and Address of Applicant (Include ZIP Code) BioNet International Corp., Agent for ORGANICA BIOTECH, INC 9619 Evans Ford Road, Manassas VA 20111 <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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION APR 11 2003
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<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.)

NOTIFICATION IS MADE OF PRODUCT LABELING CHANGES WHICH ARE CONSISTENT WITH THE PROVISIONS OF PR NOTICE 98-10, SECTIONS II.K AND II.M. FOR SUCH NOTIFICATIONS THESE LABELING CHANGES ARE DESCRIBED FULLY ON THE ATTACHED ADDITIONAL PAGE 2.

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 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 <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 12, 16, 24, & 32 fl. oz., 2, 5, 20 & 25 gal		5. Location of Label Directions <input checked="" type="checkbox"/> ON LABEL	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name FREDERICK D. OBENCHAIN	Title REGULATORY AFFAIRS AGENT	Telephone No. (Include Area Code) 703-361-3508
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 REGULATORY AFFAIRS AGENT	
4. Typed Name FREDERICK D. OBENCHAIN	5. Date 3 MARCH, 2003	

EPA Form 8570-1 (Rev. 3-94) Continued

Section – II

Explanation: *Continued – Notification dated March 3, 2003..*

Organica® K+NEEM Insecticidal Soap, EPA Reg. No. 70191-1 Label modifications by Notification.

Under provisions of PR Notice 98-10, Section K.1 and K.2, the following sentence is added to the front panel of all products specifically labeled for Home and Garden Use by this notification in order to identify the botanical source of the active ingredient.

“An easy-to-use insecticide derived from the botanical oils of the Indian Neem Tree.”

Under provisions of PR Notice 98-10, Section M.1, the appropriate form of the following sentence is added to the front panel (immediately following the preceding sentence) of all products specifically labeled for Home and Garden Use by this notification in order to specify the volume of diluted spray which can be made by dilution of each product size.


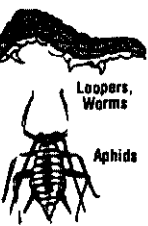



For the 12 fl. oz. product size:	“Concentrate makes 3.25 gallons of spray.”
For the 16 fl. oz. product size:	“Concentrate makes 5 gallons of spray.”
For the 32 fl. oz. product size:	“Concentrate makes 10 gallons of spray.”
For the 1 gallon product size:	“Concentrate makes 40 gallons of spray.”

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.

NOTIFICATION**APR 11 2003**

3/5

FRONT LABEL
4 1/8" x 2 3/8"



K+NEEM™

Insecticidal Soap Concentrate

ACTIVE INGREDIENT BY WT.
Potassium Salts of Fatty Acids* 25.0%
*derived from Neem Seed Oil.

INERT INGREDIENTS 75.0%
TOTAL 100.0%

Keep out of reach of children

CAUTION

See back panels for additional precautionary statements.


NET CONTENTS 16 FL. OZ.

An easy-to-use insecticide derived from the botanical oils of the Indian Neem Tree. Concentrate makes 5 gallons of spray.

For Home and Garden Use
An alcohol-free formulation of potassium soaps derived from the botanical oils of Indian Neem Tree seeds. Use as a spray to contact and kill listed pests on indoor plants, outdoor ornamental plants, flowers, shrubs and trees, and on garden vegetables, fruits and nut trees.

EXACT LABEL REPRODUCTION
EPA Reg. No. 70191-1.

Notification of 3 March, 2003



K+NEEM™

Insecticidal Soap Concentrate

32 FL. OUNCE SIZE

Label Code : 41904-1299

Page 1 of 2 Pages

BACK FOLDOUT LABEL
INSIDE PANELS: #s 1 & 2

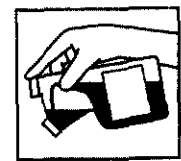
DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its label. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

READ ENTIRE LABEL. USE IN STRICT ACCORDANCE WITH LABEL DIRECTIONS & PRECAUTIONS.

GENERAL INFORMATION:
This product can be applied up to day of harvest.

MIXING AND APPLICATION: Shake or stir product thoroughly before use. Mix product with soft water whenever possible. Always use freshly mixed solutions.

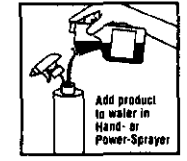
You may apply product with most types of hand or power sprayers. Be certain that spray tanks, hoses, nozzles and other sprayer parts are thoroughly clean and uncontaminated with other pesticides before use. Read and follow the instructions for the type of sprayer you use.



MEASURE



ADJUST



POUR

GENERAL USE RESTRICTIONS: Do not use on new transplants, recently rooted cuttings, drought-stressed plants or sensitive new growth. Never apply while plants are exposed to full sun; spray during early morning or evening hours when the temperature is below 85°F.

Certain plant varieties are more sensitive than others and sensitivity may appear after multiple applications. **Test a few inconspicuous leaves** of BALD CYPRESS, BEGONIAS, CAMELLIAS, CHRYSANTHEMUMS, CUCURBITS, DELICATE FERNS, EUPHORBIAS, FUCHSIAS, GRAPE, IMPATIENS, IVIES, PALMS, PEPPERS, POINSETTIAS, NARROW LEAF EVERGREENS, SCHEFFLERA and SUCCULENTS, and **flowers** of AFRICAN VIOLET, AGERATUM, AZALEA, BEGONIA, CHRYSANTHEMUM, DAHLIA, GERANIUM, IMPATIENS, LILY, MARIGOLD, PANSY, PETUNIA, SALVIA, SNAPDRAGON,

BACK FOLDOUT LABEL
INSIDE PANELS: #s 3 & 4

VINCA and ZINNIA for sensitivity before application (or reapplication) to entire plant. If wilting of leaves or flower occurs within a few hours, rinse test plants with clean water.

Do not use on drought stressed plants or on BLEEDING HEART, CROWN OF THORNS, GARDENIA, HORSE CHESTNUT, JADE PLANT, JAPANESE MAPLE, LANTANA, MOUNTAIN ASH OR SWEET-PEAS, or tender new growth of conifers. Use of this product may discolor foliage of spruce or other conifers. Surface marking may result from presence of sooty molds on foliage or fruits of some plants, particularly on citrus and some varieties of pome fruits.

PROTECT POLLINATING INSECTS: unless flowers are the target of pest species, avoid spray treatments when plants are in full bloom.

FOR HOME AND GARDEN USE:

To contact and kill most mite and insect pests, use a fresh spray by dilution of the concentrate. Make up a 1:50 spray dilution (0.5% of active ingredient) with 1 part of product to 50 parts water, or 2.5 oz. of product in 1 gallon of water. (NOTE: 2.5 oz. = 5 TBS. / 0.5 oz. = 1 TBS.)

Treat **INDOOR PLANTS** with the 1:50 spray dilution to contact and kill APHIDS, MEALYBUGS, SCALE CRAWLERS, SPIDER MITES, THRIPS & WHITEFLIES. Make sure spray penetrates through dense foliage to contact pests and wets all infested surfaces. Examine plants for aphids after two days and retreat if aphids are still present. Spray at weekly intervals if other pests are still present. Treat **AFRICAN VIOLETS** to contact and kill blossom thrips by spraying all surfaces of blossoms. Treat **AFRICAN VIOLETS, SUCCULENTS OR CACTUS** for contact and kill of ROOT MEALYBUGS by drenching pots of infested plants with a tepid 0.4% solution (0.5 oz. or 1 TBS. of product per quart of water).

Treat **ORNAMENTAL TREES, SHRUBS & PLANTS** in and around the home, or **FLOWERS, BEDDING PLANTS & ORNAMENTAL VEGETABLES**, grown outdoors or in greenhouses, with the 1:50 spray dilution to contact and kill ADELGIDS, APHIDS, IMPORTED CABBAGE WORMS, CRICKETS, EARWIGS, FLEA BEETLES, GRASSHOPPERS, GREEN STINK BUGS, GYPSY MOTH CATERPILLARS, HARLEQUIN BUGS, JAPANESE BEETLES, LACEBUGS, LEAPHOPPERS, MEALYBUGS, PLANT BUGS, PSYLLIDS, ROSE SLUGS, SAWFLIES, SCALE CRAWLERS, SPIDER MITES, SQUASH BUGS, TENT CATERPILLARS, THRIPS & WHITEFLIES.

Treat **FRUIT & NUT TREES OR BERRIES**, grown outdoors or in greenhouses, with the 1:50 spray dilution to contact and kill listed pests **up to day of harvest**. Use on ALMOND,

BACK FOLDOUT LABEL
INSIDE PANELS: #s 5 & 6

BEECHNUT, BUTTERNUT, CASHEW, CHESTNUT, FILBERT, HICKORY NUT, MACADAMIA NUT, PECAN & WALNUT to kill APHIDS & SPIDER MITES; use on GRAPEFRUIT, LEMON, LIME, ORANGE, TANGERINE, TANGELO & OTHER CITRUS HYBRIDS to kill APHIDS, SCALE CRAWLERS & SPIDER MITES; use on APPLE, CRABAPPLE, GUAVA, PEAR & QUINCE to kill ADELGIDS, APHIDS, PEAR PSYLLA, PEAR SLUG, SCALE CRAWLERS, SPIDER MITES, THRIPS & WOOLLY APHIDS; use on APRICOT, CHERRY, NECTARINE, PEACH, PLUM, & PRUNE to kill APHIDS & MITES; use on BLACKBERRY, BLUEBERRY, BOYSENBERRY, CRANBERRY, CURRENT, DEWBERRY, ELDERBERRY, FIG, GOOSEBERRY, GROUNDCHERRY, HUCKLEBERRY, KIWI FRUIT, LOGANBERRY, MULBERRY, PAWPAW, PERSIMMON, PINEAPPLE, RASPBERRY, SERVICEBERRY, STRAWBERRY, SUGAR APPLE & YOUNGBERRY to kill APHIDS & SPIDER MITES; use on GRAPE to kill APHIDS & LEAPHOPPERS; use on exotic fruit such as AVOCADO, BANANA, DATE, GRANADILLA, LOQUAT, MANGO, PAPAYA, PASSION FRUIT, POMEGRANATE, PRICKLYPEAR, SAPODILLA, SAPOTA, SHADDOCK & SOURSOP to kill ADELGIDS, APHIDS, LEAPHOPPERS, MEALYBUGS, PLANT BUGS, PSYLLIDS, SCALE CRAWLERS, SLUGS (SAWFLY LARVAE), SPIDER MITES, STINK BUGS, THRIPS, WOOLY APHIDS & WHITEFLIES.

Treat **GARDEN VEGETABLES**, grown outdoors or in greenhouses, with 1:50 spray dilution to contact and kill listed pests **up to day of harvest**. Use on EGGPLANT, OKRA, PEPPERS & TOMATOES to kill APHIDS, SPIDER MITES & WHITEFLIES; use on BROCCOLI,

BROSSELS SPROUTS, CABBAGE, CAULIFLOWER, CHARD, CHINESE CABBAGE, COLLARDS, & KALE, to kill APHIDS, CABBAGE LOOPERS, FLEA BEETLES, HARLEQUIN BUGS, IMPORTED CABBAGEWORMS, LEAF BEETLES, LEAPHOPPERS & WHITEFLIES; use on CELERY, LETTUCE, MUSTARD & OTHER GREENS, RADISH, SPINACH & TURNIPS to kill ADELGIDS, APHIDS, CATERPILLARS, FLEA BEETLES, LEAPHOPPERS & SPIDER MITES; use on CUCUMBER, PUMPKIN, SQUASH & MELONS to kill APHIDS, FLEA BEETLES, LEAF BEETLES, LEAPHOPPERS, SPIDER MITES, SQUASH BUGS & WHITEFLIES; use on BEANS, PEAS & EDIBLE SOYBEANS to kill APHIDS, LEAPHOPPERS, GRASSHOPPERS, GREEN STINK BUGS & SPIDER MITES.

In **GREENHOUSES & INDOOR PLANTSCAPES**, use 1:50 spray dilution to contact and kill LISTED PESTS as directed above.
Use a 0.4% (active) spray solution (1/2 oz. or 4 TBS of product per gallon of water) for contact and kill of GREENHOUSE WHITEFLIES. TREAT UP TO DAY OF HARVEST to kill listed pests on greenhouse or indoor food plants (vegetables, herbs, fruits & nuts).

On **LAWNS & TURF**, use 1:50 spray dilution to contact and kill CHINCH BUGS & MOLE CRICKETS. Apply at rate of 1 quart of spray per 110 sq. ft. (= 1 gallon per 440 sq. ft. or 100 gallons per acre). For best results, thoroughly water (or irrigate) treated turf at rate of 15 gallons of water per 110 sq. ft. (= 60 gallons per 440 sq. ft. or 6,000 gallons per acre) immediately after treatment.

-Continued-

BACK FOLDOUT LABEL
OUTSIDE PANELS, #s 7 & 8

DIRECTIONS FOR USE, CONT.

FOR PERSISTENT PEST PROBLEMS, re-treat with a fresh spray dilution of K+ Neem Insecticidal Soap Concentrate at the strength specified above. Apply to contact pest and thoroughly wet both surfaces of infested leaves or branches.

Re-treat after 2 or 3 days for continued contact and kill of APHIDS and MEALYBUGS. Spray ADELGIDS, PSYLLIDS and SCALES during periods of peak egg hatch and crawler activity. Spray again after 14 days. For persistent infestations of other listed pests, spray 2 or 3 times (at weekly intervals) until pest control is achieved.

LIMIT TREATMENTS to a total of three spray applications, unless accumulating soap residues are first removed by a thorough rinsing of treated foliage. **Some plant varieties become sensitive after first treatment!** Test a few leaves before repeat applications to cucurbit & pepper varieties before retreating the entire planting. If leaf or flower wilt occurs within a few hours, rinse test plants with clean water.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals: CAUTION. Harmful if inhaled. Causes moderate eye and skin irritation. Avoid contact with skin, eyes or clothing or breathing mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of practical treatment: **If in eyes** - Flush eyes with plenty of water. Call physician if irritation persists. **If on skin** - Wash with plenty of soap and water. Get medical attention if irritation persists. **If inhaled** - Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

Environmental hazards: This product may be hazardous to aquatic invertebrates. Do not apply directly to water, 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 wastes.

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.

BACK FOLDOUT LABEL
OUTSIDE PANELS, #s 9 & 10

Personal Protective Equipment: Some materials that are chemically resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Handlers who may be exposed to the diluted product through application or other tasks must wear: long-sleeved shirt and long pants, shoes plus socks.

Handlers who may be exposed to the concentrate through mixing, loading, application, or other tasks must wear: Goggles or safety glasses, coveralls over short-sleeved shirt and short pants, chemical resistant gloves such as butyl rubber, nitrile rubber, neoprene rubber or PVC, chemically resistant headgear for overhead exposure, and chemically resistant apron when cleaning equipment, mixing or loading. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations: Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

STORAGE AND DISPOSAL:

Storage: Store in cool place (preferably in a locked storage area) and keep container tightly sealed. Do not transfer or dilute into food or drink containers. Avoid contamination of feed or foodstuffs.

Disposal: PESTICIDE DISPOSAL — Dispose of unused product by securely wrapping original container in several layers of newspaper and discard in trash.

CONTAINER DISPOSAL — Do not reuse empty container. Triple rinse before discarding in trash, or offer for recycling/reconditioning, or punch and dispose of in sanitary landfill, or by incineration, or by burning if allowed by local authorities. If burned, keep out of smoke.

Notice: ORGANICA, Inc. makes no warranty, expressed or implied, for any purpose other than those contained on this label. Buyer assumes all responsibility for safety and consequences of damage or injury for product use, storage, handling or application which are not in accordance with explicit label directions. **THE LIMIT OF MANUFACTURER'S LIABILITY SHALL BE THE PURCHASE PRICE FOR THE QUANTITY INVOLVED. IN NO CASE SHALL THE MANUFACTURER BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

BACK FOLDOUT LABEL
OUTSIDE PANELS, #s 11 & 12

PANEL #11
GLUE PANEL

**K+ Neem
Insecticidal Soap
Concentrate**



5/5

Organica® Biotech, Inc.

Remarkable products from Nature's own laboratory™

Regulatory Affairs Office
c/o BioNet International Corp., Agents
9619 Evans Ford Road
Manassas, VA 20111-2699
Phone (703) 361-9508; Fax (703) 330-1809

Corporate Office, Research and Development Facility
705 General Washington Avenue, Suite 500
Norristown, PA 19403
Phone (610) 539-8300
Fax (610) 539-8383

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504c)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Transmittal Date: 3 March, 2003

BY HAND DELIVERY

TRANSMITTAL DOCUMENT FOR: Notification of label changes to EPA Registration No. 70191-1. The subjects of this notification include:

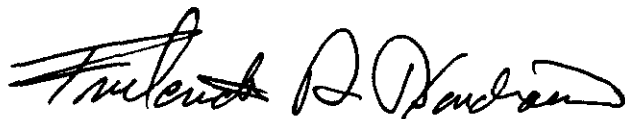
- A) Addition of a sentence on the front panel of the label identifying the product as an insecticide with an active ingredient from a botanical source under PR Notice 98-10, Sect. II.K.1 and II.K.2. and
- B) Specification of the volume of spray which can be made by dilution of the product by respective size under PR Notice 98-10, Sect. II.M.

SUBMITTED BY: Organica Biotech, Inc.
c/o BioNet International Corp., Regulatory Affairs Agents
9619 Evans Ford Rd.
Manassas, VA 20111-2699

COMPANY CONTACT: Dr. Frederick D. Obenchain - Phone: (703) 361-9508

SUBMISSION CONTENTS: This transmittal form.
EPA Form 8570-1, unnumbered, completed Application Form marked as a Notification.
Three copies of the current printed label (specimen copies mounted to 8.5" x 11"), which bears text consistent with the 16 ounce product size and with this notification.

EPA PRODUCT MANAGER: Debbie McCall



Frederick D. Obenchain, Ph.D.
Regulatory Affairs Agent