

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Washington, D.C. 20460

DEC 17 2008

James Kuntsman, Ph.D. Director Regulatory Affairs PBI/Gordon Corporation P.O. Box 014090 Kansas City, MO 64101

Subject: Azadirachtin 1.2% EC Insecticide

EPA Registration No. 2217-836

Alternate Formulation

Your submission dated August 14, 2008

Dear Dr. Kuntsman:

The alternate formulation referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has been received and reviewed, and the alternate formulation is acceptable provided that you submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. Should you have any questions, you may contact Leonard Cole directly at 703.305.5412 or via email at cole.leonard@epa.gov.

Sincerely,

Linda A. Hollis, Chief

Biochemical Pesticides Branch Biopesticides and Pollution

Prevention Division (7511P)

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AZADIRACHTIN 1.2% EC INSECTICIDE

EPA Reg. No. 2217-836

ACTIVE INGREDIENT	
Azadirachtin	1.2%
OTHER INGREDIENTS:	98.8%
TOTAL	100.0%

Contains 0.0987 lb. azadirachtin per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

STOP! READ THE ENTIRE LABEL FIRST. OBSERVE ALL PRECAUTIONS AND FOLLOW DIRECTIONS CAREFULLY.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if absorbed through skin or if inhaled. Avoid breathing vapor. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

First Aid	
If on skin or clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If inhaled:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice
If in eyes:	 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of medical emergency involving this product, you may call toll free, 1-877-800-5556 for additional treatment information.

ACCEPTED

DEC 1 7 2008

An Employee-Owned Company
1217 West 12th Street
Kansas City, Missouri 64101

Under the Federal Ineacticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under TPA Rea. No. 27/7 52/6

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long sleeved shirt and pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

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.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. For terrestrial uses: 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 cleaning equipment or disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

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

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.

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 worker entry into treated areas during the restricted-entry interval (REI) of 4 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
- · Waterproof gloves
- · Shoes plus socks

Non-Agricultural Use Requirements

These requirements apply to uses of this product that are NOT within the scope of the Worker Protection Standard (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 greenhouse. For other uses, including golf courses and other non-agricultural uses, do not enter treatment areas without protective clothing until sprays have dried.

Read entire label. Use strictly in accordance with precautionary statements and directions, and with applicable state and federal regulations.

This is an end use product. PBI/Gordon Corporation does not intend that this product be reformulated or repackaged except under a toll repackaging agreement.

PRODUCT DESCRIPTION:

Azadirachtin 1.2% EC Insecticide is a botanical product for control of insects on indoor and outdoor plants including ornamental trees, shrubs, flowers, garden vegetables, turfgrass, fruit trees and nut trees.

Azadirachtin 1.2% EC Insecticide has repellent, anti-feedant and acts as an oviposition deterrent for some insects. When used as a component of an Integrated Pest Management (IPM) program, Azadirachtin 1.2% EC Insecticide provides an effective resistance management tool.

MODE OF ACTION:

Azadirachtin 1.2% EC Insecticide controls target pests on contact or by ingestion. The product acts on pests by way of repellence, anti-feedance, and interference with the molting process.

Azadirachtin, an insect growth regulator (IGR), mimics the pests' hormones and disrupts distinct stages of growth and development of insects and mites. The primary mode of action of azadirachtin is an interference with synthesis and metabolism of ecdysone and the juvenile hormone. Ecdysone is the molting hormone of insects, and azadirachtin can regulate growth leading to death before or during molting.

INDOOR AND OUTDOOR ORNAMENTAL TREES, SHRUBS, FLOWERS, AND PLANTS ESTABLISHED IN RESIDENTIAL, LANDSCAPE PLANTINGS AROUND INSTITUTIONAL, PUBLIC, COMMERCIAL AND INDUSTRIAL BUILDINGS, PARKS, RECREATIONAL AREAS, GREENHOUSES, SHADECLOTHS, NURSERIES, AND ATHLETIC FIELDS.

Azadirachtin 1.2% EC Insecticide has been evaluated for phytotoxicity on a wide range of ornamentals and crops. However, since testing on all plant varieties is not feasible, test a small portion of the area to be treated for phytotoxicity before treating the entire area. All possible combinations or sequences of pesticide sprays, including other fertilizers, surfactants, adjuvants and other pesticides have not been tested. Thus, testing for phytotoxicity of spray mixtures is recommended.

The professional user assumes the responsibility for determining the level of tolerance of treated plants to Azadirachtin 1.2% EC Insecticide when applied alone or in tank-mix combinations under commercial growing conditions.

Waxy bloom on certain ornamental plants may be reduced after an Azadirachtin 1.2% EC Insecticide application.

Applications of Azatrol may remove the glaucus 'blue' coloring from evergreens such as Colorado blue spruce and Koster spruce.

Use Azadirachtin 1.2% EC Insecticide on the following plants:

Ornamental Plants and Flowers including but not limited to:

Actinopteris, African violets*, ageratum, aglaonema, Algerian ivy, allamanda, alocasia, amaranthus, anthurium, aphelandra, arborvitae, Artemisia, aster, aucuba ilex, azalea, baby's breath, begonia, Boston fern, bougainvillea, boxwood, brachycome, cacti, calabrese, caladium, calathea, calendula, calla, camellia, carnation, ceanothus, chrysanthemum, cineraria, coleus, columbine, cotoneaster, cyclamen, daffodil, dahlia, daisy, daylily, delphinium, dianthus, dieffenbachia, dogwood, dusty miller, Easter lily, English ivy, euphorbia, fern, ficus, foliage plants, foxglove, freesia, fuschia, gaillardia, gardenia, geranium, gerbera, gladiola, gloxinia, gypsophilla, hedera, hibiscus, hyacinth, hydrangea, ilex, impatiens, iris, ivy, jasmine, lilac, lily, maidenhair fern, mandevilla, marigold, narcissus, nasturtium, orchid*, pansy, pelargonium, peony, peperomia, petunia, philodendron, phlox, photinia, pinks, pittosporum, poinsettia*, pothos, portulaca, primrose, pyracantha, rhododendron, rose, rosemary, rubber plant, salvia, schefflera, sedum, sempervivum, snapdragon, spathiphyllum, stock, syngonium, tulip, verbena, vinca, wandering jew, yucca, zinnia

* Caution is recommended when making applications to these species. Spotting of plant foliage and blossoms is possible.

Ornamental Trees and Shrubs including but not limited to:

Andromeda, arborvitae, ash, Austrian pine, azalea, beech, birch, birdsnest spruce, blue spruce, bougainvillea, boxwood, butternut, cedar, charmaecyparis, cherry, cotoneaster, crabapple, cyprus, dogwood, Douglas fir, elm, euonymus, firethorn, forsythia, hackberry, hawthorn, hemlock, hickory, holly, honey locust, horse chestnut, juniper, larch, laurel, lilac, linden, London planetree, magnolia, mandevilla, maple, mimosa, mountain ash, myrtle, oak, pachysandra, peach, photinia, pine, planetree, poplar, privet, purpleleaf wintercreeper, quince, sage, spruce, sycamore, white cedar, white pine, yew

PESTS CONTROLLED OR SUPPRESSED

Use Azadirachtin 1.2% EC Insecticide against the following pests presented in Table 1.

TABLE 1. TARGET PEST SPECIES OF AZADIRACHTIN 1.2% EC INSECTICIDE.

HEMIPTERA AND HOMOPTERA

including but not limited to:

true bugs including boxelder bugs, chinch bugs, lygus bugs and stink bug;

lacebugs; leafhoppers including grape leafhopper, spittlebug, potato leafhopper and variegated leafhopper; mealy bugs including apple mealy bugs, citrus mealy bugs, grape mealy bugs;

whiteflies including greenhouse whitefly, silverleaf whitefly and sweet potato whitefly and woolly whitefly; aphids including apple aphid, green peach aphid, melon aphid, pea aphid, potato aphid and rose aphid; psyllids including pear psyllids and

scales including black scale, brown soft scale,
California red scale, coffee scale, olive scale, San Jose
scale, and cottony cushion scale.

LEPIDOPTERA

including but not limited to:

moths including European pine shoot moth, pine tip moth and Tussock moth;

leafrollers including blueberry leafroller, filbert leafroller, fruitree leafroller, citrus leafminers, grape leafroller, oblique banded leafroller, omnivorous leafroller; cutworms including black cutworm and citrus cutworm; caterpillars and loopers including bagworms, budworms, cabbage looper, canker worms, case bearers, caseworms, corn earworm, diamondback moth, fruit worms, grapeleaf skeletonizer, gypsy moth, hornworms, imported cabbageworm, navel orangeworm, soybean looper, spruce budworm, tent caterpillar, tip moths, tent caterpillars, tobacco budworm, tobacco hornworm, tomato pinworm and tussock moth;

armyworms including beet armyworm, fall armyworm, lawn armyworm, southern armyworm and yellow striped armyworm;

webworms and leaf perforators.

COLEOPTERA

including but not limited to:

beetles, grubs and weevils including Asian longhorned beetle, bark beetles, black vine weevil, Colorado potato beetle, elm bark beetle, European chafer, flea beetles, Japanese beetle, June beetle, leaf beetles, Mexican bean beetle, Northern masked chafer, rose chafer and Southern masked chafer and twig girdlers.

DIPTERA

including but not limited to:

flies including Caribbean fruit fly, cherry maggots, crane fly,

fungus gnat, Hessian fly, oriental fruit fly, Mediterranean fruit fly, marsh crane flies, melon fly, shore fly and walnut husk fly:

leafminers including citrus leafminers and serpentine leafminers.

THYSANOPTERA including but not limited to: thrips including citrus thrips, flower thrips, gladiolus thrips, onion thrips, thrips palmi and Western flower thrips.	ACARINA including but not limited to: mites, red spider mites, brown mite, clover mite, conifer spider mite, European red mite, spruce spider mite, and two-spotted spider mite.
ORTHOPTERA including but not limited to: crickets; grasshoppers; locusts	HYMENOPTERA including but not limited to: sawflies including European sawflies, pear sawflies, redheaded pine sawflies, yellow-headed pin sawflies.
NEMATODA nematodes (suppression)	

SPRAY PREPARATION

Azadirachtin 1.2% EC Insecticide is an emulsifiable concentrate to be diluted with water.

Water as diluent:

Add one-half the required amount of water to the spray tank, then add Azadirachtin 1.2% EC Insecticide slowly with agitation, and complete filling the tank with water. To prevent separation of the emulsion, mix thoroughly and continue agitation while spraying.

This product forms an emulsion and can separate upon extended or prolonged standing. Re-agitate to assure uniformity of the spray mixture.

It is suggested that the water pH be 5 to 7. Do not use tank additives that alter the pH of the spray solution above pH 7. Buffer the spray solution to alter the pH range as appropriate.

Prepare only the volume needed for the intended application, and use the spray mixture within 24 hours of preparation.

TANK MIXTURES

Azadirachtin 1.2% EC Insecticide is an emulsifiable concentrate and is compatible with commonly used pesticides and fertilizers. Always check the physical compatibility using a jar test in the correct proportions if needed.

If a broader spectrum of control is required tank-mix Azadirachtin 1.2% EC Insecticide with insecticides or miticides. If a rapid knockdown of heavy populations is necessary, then include an effective contact insecticide/miticide in combination with Azadirachtin 1.2% EC Insecticide.

Tank mixture recommendations are for use only in states where the companion product(s) and the application site are registered.

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.

Select the right companion products:

IPM uses a variety of control options including biological, chemical, and cultural practices. Azadirachtin is botanical with growth regulator effect on insects and mites. Companion products include pyrethroids, spinosyns, microbial toxins, and chloronicotinyls that can complement azadirachtin. Formulations of bifenthrin, spinosad, abamectins, and imidacloprid are effective for different pests. Select the product that has been proven to provide adequate performance for the pests you are trying to control.

Physical Incompatibility

Do not use Azadirachtin 1.2% EC Insecticide with Captan, Bordeaux mixture, triphenyltin hydroxide, lime sulfur, Rayplex iron or other highly alkaline materials as they can cause phytotoxicity and/or reduced efficacy on some target pests. Tank-mix combinations with compounds known to be incompatible with oil-based formulations are not to be used or phytotoxicity may occur.

ADJUVANTS

The addition of adjuvants may enhance control under certain conditions; the use of adjuvants or oils may cause phytotoxicity and should be thoroughly tested prior to use. Do not add crop oils to spray mixtures intended for use on ornamental plants, flowers, trees, and shrubs.

APPLICATION EQUIPMENT

Ground Equipment

Apply Azadirachtin 1.2% EC Insecticide with hand-operated (manual) or power spray equipment suitable for low volume and/or high volume applications. Follow the recommendations of the equipment manufacturer when using backpack sprayers, hose-end sprayers, compression (pump-up) sprayers, and other sprayers suitable for foliar applications of insecticides.

Chemigation and Subsurface Equipment

Azadirachtin 1.2% EC Insecticide may also be applied through chemigation systems and sub-soil treatment equipment; always follow equipment manufacturer's directions.

APPLICATION SCHEDULE

For the most effective control, apply the product when pests are expected to appear or as soon as possible after pests appear and are in immature stages. Spray at an interval of seven (7) to ten (10) days or as the situation warrants.

During high pest infestation levels or when canopy is dense use higher dosage (use) rates and increase the spray frequency. Spraying in the morning or evening hours is recommended. Repeat spraying if rain occurs within two to three hours of spraying.

For additional guidance, consult with the state agricultural experiment station or local extension horticulturalist/arborist for information on tactics and windows of application.

APPLICATION RATES

Use Azadirachtin 1.2% EC Insecticide on ornamental pests as a spray concentration of 0.25 to 1.70% vol/vol per treatment with high volume applications in Table 2.

The application rates are specified as rate ranges depending upon the pest infestations:

Lower rate ranges with a spray concentration of 0.25 to 0.75% vol/vol: Use lower rate ranges for light infestations of lepidopterous insects, at the first sign or at the first observation of the early and uniform growth stages of the pest(s), and/or tank mixtures with contact insecticides.

Medium rate ranges with a spray concentration of 0.75 to 1.25% vol/vol: Use medium rate ranges for moderate infestations, when multiple growth stages of the pests are present, and/or heterogeneous pesticide populations are present.

Upper rate ranges with a spray concentration of 1.25 to 1.70% vol/vol: Use upper rate ranges for moderate to heavy pest populations of difficult-to-control pest species, for the late stages of larva/worms, for dense foliage, and/or when re-infestations occur.

High Volume Applications:

Apply Azadirachtin 1.2% EC Insecticide at spray concentration of 0.25 to 1.70% v/v in sufficient amounts of water to achieve complete coverage. Use an adequate spray volume to wet the leaves (foliage) and stems. Spray volumes will vary with the plant size.

Attempt to penetrate dense foliage. Thorough coverage of the upper and lower leaf surfaces is critical for effective levels of control.

Refer to Table 3 for the amounts of Azadirachtin 1.2% EC Insecticide required to prepare spray concentrations of 0.25% to 1.70% for spray volumes of 1 gallon to 200 gallons.

Specialized Low Volume Applications:

Select a spray volume to achieve sufficient coverage. Uniform coverage of both upper and lower leaf surfaces is critical for effective insect control.

Apply Azadirachtin 1.2% EC Insecticide in a *minimum* spray volume of 5 gallons per acre. Larger plants will require the higher spray volumes (20 to 25 gallons per acre) to obtain sufficient coverage.

Do not exceed 20 grams active ingredient per acre per application or 57 fl.oz. of product per acre per application.

Refer to Table 4 for the amounts of Azadirachtin 1.2% EC Insecticide required to prepare spray concentrations of 0.25% to 1.70% for spray volumes of 5 to 25 gallons per acre.

TABLE 2. APPLICATION RATES FOR ORNAMENTALS ESTABLISHED IN RESIDENTIAL, LANDSCAPE PLANTINGS AROUND INSTITUTIONAL, PUBLIC, COMMERCIAL AND INDUSTRIAL BUILDINGS, PARKS, RECREATIONAL AREAS, GREENHOUSES, SHADECLOTHS, NURSERIES, AND ATHLETIC FIELDS

	AL AREAS, GREENHOU	SPRAY		adirachtin 1.2% EC	
USE	PESTS	CONCENTRATION %	Fluid ounces	Fluid ounces	Quarts per
			per gallon	per 100 gallons	100 gallons
Including trees,		Lower rate ranges of	0.32 to 1.0	32 to 96	1.0 to 3.0
shrubs,	Azalea caterpillars	0.25 to 0.75% vol/vol:	fl.oz.	fl.oz.	qts.
flowers,	Aphids	,			•
conifers,	Bagworms	Madium rata ranga	1.00 4.1.60	96 to 160	204050
evergreens, herbaceous	Black vine weevils	Medium rate ranges of 0.75 to 1.25%	1.00 to 1.60 fl.oz.	96 to 160 fl.oz.	3.0 to 5.0
ornamentals,	Boxelder bugs Budworms	vol/vol:	11.02.	11.02.	qts.
foliage plants,	Cankerworms	VOI/VOI.			•
container-	Cutworms				•
grown	Eastern tent caterpillars	Upper rate ranges of	1.60 to 2.18	160 to 218	5.0 to 6.8
ornamentals.	Elm leaf beetles	1.25 to 1.70% vol/vol:	fl.oz.	fl.oz.	qts.
plants and	European sawflies	1.25 to 1.70% volvoi.	11.02.	11.02.	yıs.
groundcovers	Fall webworms				
groundcovers	Flea beetles				
	Forest tent caterpillars				
	Gypsy moth larvae				•
	Japanese beetles				
	June beetles				
	Lace bugs				
	Leaf-feeding caterpillars	·			-
,	Leafhoppers				
	Leafminers				
	Leaf rollers			'	
	Leaf skeletonizers				
	Oleander moth larvae				į
	Pine sawflies				
	Pine shoot beetles				
	Pinetip moths				
	Plant bugs			ľ	
	Sawflies (larva)				i
	Scale insects (crawlers)				
	Spruce budworm				
i	Striped beetles	·			
	Striped oakworms		\$	1	'
	Thrips Tussock moth larvae ,				
*	Brown softscale	•		1	
	California redscale				
	(crawler)			\	
	Clover mites				
	Mealybugs				
	Pineneedlescale				•
	(crawler)			1	
	Spider mites		•		
	Whiteflies		·		
	and other species			,	
	identified in Table 1				

Gallons	Amounts of Azadirachtin 1.2% EC Insecticide For:							
Of Water	0.25%	0.50%	0.75%	1.00%	1.25%	1.50%	1.70%	
1 gallon	0.32 fl.oz.	0.64 fl.oz.	0.96 fl.oz.	1.28 fl.oz.	1.60 fl.oz.	1.94 fl.oz.	2.18 fl.oz.	
5 gallons	1.60 fl.oz.	3.2 fl.oz.	4.8 fl.oz.	6.4 fl.oz.	8.0 fl.oz.	9.7 fl.oz.	10.9 fl.oz.	
10 gallons	3.2 fl.oz.	6.4 fl.oz.	9.6 fl.oz.	12.8 fl.oz.	16.0 fl.oz.	19.4 fl:oz.	21.8 fl.oz.	
25 gallons	8.0 fl.oz.	16.0 fl.oz.	24.0 fl.oz.	32 fl.oz.	1.25 qts.	1.50 qts.	1.70 qts.	
50 gallons	16.0 fl.oz.	32.0 fl.oz.	1.50 qts.	2.0 qts.	2.5 qts.	3.0 qts.	3.4 qts.	
100 gallons	1.0 qt.	2.0 qts.	3.0 qts.	4.0 qts.	5.0 qts.	6.0 qts.	6.8 qts.	
150 galions	1.5 qts.	3.0 qts.	4.5 qts.	6.0 qts.	7.5 qts.	9.0 qts.	10.2 qts.	
200 gallons	2.0 qts.	4.0 qts.	6.0 qts.	8.0 qts.	10.0 qts.	12.0 qts.	13.6 qts.	

Spray Concentration	Spray Volume, Gallons Per Acre						
Desired, % vol/vol	5 gpa	10 gpa	15 gpa	20 gpa	25 gpa		
0.25% v/v	1.6 fl.oz./acre	3.2 fl.oz./acre	4.9 fl.oz./acre	6.5 fl.oz./acre	8.0 fl.oz./acre		
0.50% v/v	3.2 fl.oz./acre	6.4 fl.oz./acre	9.6 fl.oz./acre	12.8 fl.oz./acre	16.0 fl.oz./acre		
0.75% v/v	4.8 fl.oz./acre	9.6 fl.oz./acre	14.4 fl.oz./acre	19.2 fl.oz./acre	24.0 fl.oz./acre		
1.00% v/v	6.4 fl.oz./acre	12.8 fl.oz./acre	19.2 fl.oz./acre	25.5 fl.oz./acre	32.0 fl.oz./acre		
1.25% v/v	8.0 fl.oz./acre	16.0 fl.oz./acre	24.0 fl.oz./acre	32.0 fl.oz./acre	40.0 fl.oz./acre		
1.50% v/v	9.6 fl.oz./acre	19.2 fl.oz./acre	28.9 fl.oz./acre	38.5 fl.oz./acre	48.0 fl.oz./acre		
1.70% v/v	10.8 fl.oz./acre	21.6 fl.oz./acre	32.5 fl.oz./acre	43.3 fl.oz./acre	54.0 fl.oz./acre		

SPECIFIC USE INSTRUCTIONS:

Decision-making for IPM:

Scouting, monitoring, sampling, record-keeping, and predictive models are techniques to determine *if* and *when* insecticide/miticide applications are needed. The application schedule should coincide with the most vulnerable stage of the pest. For azadirachtin, target the most vulnerable stages of young larvae and young nymphs. The early larval stages and the early instar stages are more susceptible to this IGR than the later stages of the same pests.

For Lepidoptera:

- Armyworms. Apply when larvae are small.
- Bagworms: Apply when bags are small and larvae are actively feeding.
- Gypsy moth larvae: Apply when larvae are small and all eggs have hatched.
- Spruce budworms: Apply when larvae are exposed and actively feeding.

For Acarina:

• Spider mites: Apply when nymphs are first observed and before mite populations have become severe. Use multiple applications with 7 to 10 day intervals until infestation is controlled. Thorough coverage of both upper and lower leaf surfaces is needed.

For Thysanoptera:

Thrips: Apply early at first signs of infestation and repeat until infestation is controlled.

For Hymenoptera:

Sawfly: Apply when larvae are small. Refer to tree injection method of this label.

For Hemiptera and Homoptera:

- Leafhoppers: Apply when first observed and repeat applications at 5 to 7 day intervals.
- Mealybugs: Obtain thorough coverage of leaves and twigs.
- Scale: Obtain thorough coverage of leaves and twigs.

For Coleoptera:

- Beetles: Apply early at first signs of infestation and repeat applications at 7 to 10 day intervals.
- Japanese beetle (adults): Use foliar applications to repel adult feeding and treat at 5 to 7 day intervals.

For Diptera:

• Leafminers: Apply early to larvae when stippling or mining of leaves is first observed. Repeat applications at 7 to 10 day intervals until infestation is controlled.

TURFGRASS ESTABLISHED IN RESIDENTIAL (LAWNS), INSTITUTIONAL, PUBLIC, COMMERCIAL AND INDUSTRIAL SITES, PARKS, RECREATIONAL AREAS, GOLF COURSES, SOD FARMS, AND ATHLETIC FIELDS

Use Azadirachtin 1.2% EC Insecticide to control the pests presented in Table 5. Dilute Azadirachtin 1.2% EC Insecticide in water.

The most vulnerable stage to this product is young larvae and nymphs. Schedule treatments for the early larval stages and early instars when populations are established, but before turf damage becomes noticeable.

The maximum rate on turfgrass of Azadirachtin 1.2% EC Insecticide is 57.0 fl.oz. of product per acre per application or 1.3 fl.oz. product per 1,000 sq.ft. per application. Apply at a rate up to 57 fl.oz. of product per acre. Use the higher rate specified on this label for moderate to heavy infestations.

Irrigation:

Avoid (delay or postpone) irrigation for 12 to 24 hours after application of this product.

Mowing:

Avoid (delay or postpone) mowing of the treated area for 12 to 24 hours after treatment.

Degree day and plant phenology models can assist in developing the appropriate application schedule for the target pests. Consult your state university or local Cooperative Extension Service office for specific pest control application timing in your area.

Azadirachtin 1.2% EC Insecticide can be tank mixed with other insecticide/miticides if a broader spectrum of pest control is required. Observe all precautionary statements and follow all label directions of companion product(s).

Specific Use Instructions:

- 1. Armyworms: Apply during the early morning or late afternoon to maximize control.
- 2. Sod webworm larvae: Applications in the late afternoon or early evening can maximize control.

TABLE 5. APPLICATION RATES FOR TURFGRASS ESTABLISHED IN RESIDENTIAL (LAWNS), INSTITUTIONAL, PUBLIC, COMMERCIAL AND INDUSTRIAL SITES, PARKS, RECREATIONAL AREAS, GOLF COURSES, SOD FARMS, AND ATHLETIC FIELDS.

USE	PESTS	Amount of Azadirachtin 1.2% EC Insecticide		Spray Volumes		Number of Applications
USE	PE313	fl.oz./acre	fl.oz./1,000 sq.ft.	gals./acre	gals./1000 sq.ft.	& Interval Days
Cool-Season and Warm- Season Turfgrass	Larvae and nymphs of these pests including but not limited to: Armyworms, Bermudagrass mite, Cutworms, Grasshopper, Sod webworm, Ticks, Chiggers	Up to 57.0 fl.oz.	Up to 1.3 fl.oz.	40 to 100 gpa	1 to 2 gal/1,000 sq.ft.	As needed, 7 days

DRENCH APPLICATION FOR GREENHOUSES, NURSERIES, INTERIORSCAPES AND FOR PLANTS GROWN IN CONTAINERS:

Use Azadirachtin 1.2% EC Insecticide as a soil drench for effective control of soil-borne insect larvae, including soil-borne larvae of foliar pests, such as fungus gnats, nematodes, or soil borne thrips. When applying as a drench, avoid excessive leaching.

Preventive applications as a soil drench may be warranted for certain pests. Soil drench applications of azadirachtin will have a slower rate of activity because of soil absorption when compared to foliar applications of azadirachtin. Target the initial application of a soil drench treatment to coincide with the early stages of young larvae and young nymphs.

Dilute Azadirachtin 1.2% EC Insecticide with water for concentrations of 0.4 to 0.8% vol/vol. Drench the soil in the pot with one (1) pint of finished spray per 1.0 gallon of soil. For fungus gnats, use the 0.4% spray concentration. For mushroom fly maggot control, use the 0.6% vol/vol spray concentration. For leafminers and other difficult to control pests, use the 0.8% vol/vol spray concentration. Two to three (2-3) applications should be scheduled at 10 to 14 day intervals until the pest pressure has ended.

ILUTION TABLE	FOR DRENCH AP	PLICATIONS			
Gallons of	Amount of A	Amount of Azadirachtin 1.2% EC Insecticide			Number of
Water	0.4%	0.6%	0.8%	Interval	Applications
1 gallon	1 Tbs.	1.5 Tbs.	2.0 Tbs.	10 to 14 days	2 to 3
5 gallons	2.7 fl.oz.	4.0 fl.oz.	5.5 fl.oz.	10 to 14 days	2 to 3
10 gallóns	5.4 fl.oz.	8.0 fl.oz.	11.0 fl.oz.	10 to 14 days	2 to 3
100 gallons	1.7 qts.	2.5 qts.	3.4 qts.	10 to 14 days	2 to 3

Azadirachtin 1.2% EC Insecticide can also be applied through sub-surface treatment equipment. Always follow manufacturer's use directions.

TREE INJECTION

Inject Azadirachtin 1.2% EC Insecticide into mature trees established in landscapes, residential settings, nurseries, and forestry sites.

Use appropriate tree injection equipment and follow the instructions provided by the equipment manufacturer.

Application Schedule For Tree Injections

Consult with your state agricultural experiment station, extension specialist, or your local U.S. Forest Service authority for information on the application schedule for specific pests in your area.

PESTS	HOSTS
Spruce budworm larva	White Spruce Black Spruce Balsam Fir
Pine false webworm	Eastern White Pine Red Pine
Pine sawfly larvae	White Pine
Cedar leafminer	White Cedar

Dosage Rate For Tree Injections

Use appropriate injection equipment. Inject at the rate of 0.37 to 0.74 fl.oz. (11 to 22 ml) of product per inch tree trunk diameter at breast height. Or, inject at the rate of 0.127 to 0.25 grams azadirachtin per inch tree trunk diameter at breast height.

INSTRUCTIONS FOR GARDEN CROPS, VEGETABLES, HERBS AND SPICES, FRUITS, AND BERRIES

- For the most effective control, spray the product as soon as possible after pests appear and are in immature stages.
- Spray at an interval of seven to ten days or as the situation warrants. During high pest infestation levels use higher label rates and increase the spray frequency.
- Spraying in the morning or evening hours is recommended.
- Repeat spraying if rain occurs within two to three hours of spraying.

SPRAY EQUIPMENT

Use any suitable application equipment to ensure uniform coverage.

USE RATES

Apply Azadirachtin 1.2% EC Insecticide as directed to any food or non-food crop up to and including the day of harvest, at a maximum rate of 57 fl.ozs. (20 grams active ingredient) per acre (1.33 fl.ozs. per 1,000 sq.ft.) per application. Rates in Table 6 pertain to typical pest infestations.

Apply Azadirachtin 1.2% EC Insecticide alone to food/garden crops on the day of harvest.

Dilute this product with water at 0.5 to 4.0 tablespoons (Tbs) per gallon of water. For hose end sprayers, set the RATE PER GALLON at the dial setting of 1 to 4 Tbs. depending on the crop and pests. Use the lower RATE PER GALLON for low to moderate infestations and use the higher specified RATE PER GALLON for severe infestations.

TABLE 6. USE RATES FO	R GARDEN CROPS, VEGETABLES,	HERBS AND SPICES,	BERRIES AND FRUIT.
		e for Sprayers	
CROP	PESTS such as:	FI.Ozs. of product per 1,000 Sq.Ft.	Tbs. of product per 1.0 gallon of water
Leafy Vegetables including but not limited to: Broccoli, Brussels Sprouts,	Leafrollers, Cutworms, Loopers, Armyworms	0.19 to 0.96 fl.ozs.	3/4 Tbs. to 4 Tbs./gal
Cabbage, Cauliflower, Collards, Endive, Kale, Lettuce, Spinach	True Bugs, Leafhoppers, Whiteflies, Aphids, Beetles, Weevils, Flies, Thrips, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal

TABLE 6. USE RATES FO	R GARDEN CROPS, VEGETABLES	HERBS AND SPICES	, BERRIES AND FRUIT.
		Dilution Ra	te for Sprayers
CROP	PESTS such as:	Fl.Ozs. of product per 1,000 Sq.Ft.	Tbs. of product per 1.0 gallon of water
Root Vegetables, including but not limited to: Beet,	Beetles, Weevils	0.11 to 0.22 fl.ozs.	1/2 Tbs. to 1.5 Tbs /gal
Carrot, Horseradish, Parsnip, Potato, Radish, Sweet potato, Turnip, Yams	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Thrips, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Fruiting Vegetables	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
including but not limited to: Eggplant, Pepper, Tomatillo, Tomato	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
,	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Cucurbit Vegetables including but not limited to:	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Cucumber, Gourd (edible), Muskmelon,	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Pumpkin, Squash, Watermelon, including Cantaloupe, Casaba, Gherkins, Melons (including hybrids),	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Zucchini Legume Vegetables	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
including but not limited to: Bean, Chickpea, Lentil, Pea	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Bulb Vegetables including but not limited to: Garlic,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Onion, Shallot	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Berries including but not limited to: Blackberry,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Blueberry, Raspberry, Strawberry, others	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
include: Boysenberry, Currants, Dewberry, Elderberry, Gooseberry, Loganberry	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal

TABLE 6. USE RATES FOR GARDEN CROPS, VEGETABLES, HERBS AND SPICES, BERRIES AND FR			BERRIES AND FRUIT.
CROP	PESTS such as:	Dilution Rate for Sprayers	
		FI.Ozs. of product per 1,000 Sq.Ft.	Tbs. of product per 1.0 gallon of water
Herbs and Spices including but not limited to: Chive,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Dill, Fennel, Mustard, Sage, Sweet bay, others	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
include: Anise, Balm, Basil, Black pepper, Borage, Caraway, Catnip, Chamomile, Coriander, Cumin, Curry leaf, Dandelion, Fenugreek, Horehound, Hyssop,	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Marjoram, Marigold, Mint, Nasturtium, Pennyroyal, Peppermint, Rosemary, Savory, Spearmint,			
Tansy, Tarragon, Thyme, Wintergreen, Woodruff, Wormwood	· .	·	
Nut Trees including but not limited to: Almond, Brazil	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
nut, Filbert, Hickory nut, Pecan, Pistachios, Walnut		0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Pome Fruits including but not limited to: Apple, Pear,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Quince	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Stone Fruits including but not limited to: Apricot,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs: to 4 Tbs./gal
Cherry, Nectarine, Peach, Plum	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal
Citrus Fruits including but not limited to: Grapefruit,	Beetles, Weevils	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Lemon, Lime, Orange others include: Citrus	Thrips	0.29 to 0.96 fl.ozs.	2 Tbs. to 4 Tbs./gal
Citron, Mandarin (tangerine), Nectarine, Satsuma (orange mandarin), Tangerine	True Bugs, Leafhoppers, Whiteflies, Aphids, Leafrollers, Cutworms, Loopers, Armyworms, Flies, Mites	0.24 to 0.96 fl.ozs.	1 Tbs. to 4 Tbs./gal

CHEMIGATION GENERAL INFORMATION

Azadirachtin 1.2% EC Insecticide may be applied through drip (trickle) or sprinkler irrigation systems. Do not apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues can result from non-uniform distribution of treated water. Questions concerning calibration should be directed to your State Extension Service Specialist, the equipment manufacturer or other expert.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. Direct your questions concerning calibration to your State Extension Service Specialist, the equipment manufacturer, or other expert. A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of a responsible person, shall shut the system down and make necessary adjustments should the need arise.

Dilute Azadirachtin 1.2% EC Insecticide with water before introduction into the system. Use the diluted solution within 8 hours. Do not apply in irrigation water if the pH exceeds 7.0. The optimum pH range for application is 5.5 to 6.5. The pH of the irrigation water can be adjusted by use of a suitable buffering agent. Agitation is necessary. Apply at the specified rate using sufficient water to achieve an even distribution within an 8-hour period. Do not apply Azadirachtin 1.2% EC Insecticide at a rate that exceeds 3.5 pints active ingredient per acre (57 fl. oz).

Caution must be exercised in irrigation waters with a pH greater than 7. If the irrigation cycle will last longer than 8 hours and the Azadirachtin 1.2% EC Insecticide is premixed in the supply tank, the tank mix must be buffered to a pH of 8 or lower.

Precautions For Chemigation Systems Connected To A Public Water System

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of a year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction.

There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top of overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in the cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speeds favor drift beyond the area intended for treatment.

Operation Of Sprinkler Chemigation Or Drip (Trickle) Utilizing A Pressurized Water And Pesticide Injection System: The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid toward the injection pump. The pesticide injection pipeline must also contain a

functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse container.

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

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: <u>FOR PLASTIC CONTAINERS</u> - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed, by state and local authorities by burning. If burned stay out of smoke. <u>FOR METAL</u> <u>CONTAINERS (DRUMS)</u> - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of container in a sanitary landfill, or by other procedures approved by state and local authorities.

DISPOSAL INSTRUCTIONS FOR RESIDENTIAL/HOUSEHOLD USE:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants only that the chemical composition of this product conforms to the ingredient statement given on the label, and that the product is reasonably suited for the labeled use when applied according to the Directions for Use.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE MANUFACTURER NEITHER MAKES NOR INTENDS ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHICH ARE EXPRESSLY DISCLAIMED. This limited warranty does not extend to the use of the product inconsistent with label instructions, warnings or cautions, or to use of the product under abnormal conditions such as drought, excessive rainfall, tornadoes, hurricanes, etc. These factors are beyond the control of the manufacturer or the seller. Any damages arising from a breach of the manufacturer's warranty shall be limited to direct damages, and shall not include indirect or consequential damages such as loss of profits or values, except as otherwise provided by law.

The terms of this Limited Warranty and Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or agent of the seller is authorized to vary or exceed the terms of this Limited Warranty and Disclaimer in any manner.

APPENDIX

- 1. Statements which may appear on different label components depending on packaging configuration.
 - See next panel for additional Precautionary Statements and First Aid
 - Net Contents: _____
 - EPA Est. No.
- 2. Advertising claims that may be presented on container labeling, advertisements, brochures, and other marketing/sales promotional materials:
 - Botanical insecticide, repellant, anti-feedant and insect growth regulator (IGR)
 - Biological product for control of insects on indoor and outdoor trees, shrubs, flowers, fruit and nut trees, garden vegetables and plants.
 - Indoor and outdoor vegetables, ornamental flowers, trees, turfgrass, shrubs and plants, including plants grown in containers, interiorscapes, home and garden use.
 - · Controls mites, caterpillars, whiteflies, thrips, aphids, and other insects as listed on this label.
 - Organic certified
 - · Controls chewing and sucking insects
 - Seven to Fourteen (7 to 14) day residual
 - · Tank-mix flexibility
 - CAUTION signal word
 - Low-odor formulation
 - Broad-spectrum control
 - Can be applied the day of harvest
 - For use on a wide variety of trees, shrubs, flowers, fruit and nut trees, garden vegetables and plants
 - · Low (Mild) odor
 - Not persistent in the environment
 - [Organic Materials Review Institute (OMRI) Certified pending]
 - This product is intended for homeowner fruit and vegetable gardens other than commercial crop production.

DOCUMENT CONTROL INFORMATION

- 1. Unique Label Identifier: 002217-00836.20080806.proposed.doc
- 2. Reason for Issue: Amendment to convert from repack to me-too registration. Re-format label.