



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 30, 2021

Ms. Amy Plato Roberts
Director of Regulatory Affairs - Americas
Danstar Ferment AG/Lallemand Plant Care
PO Box 990
HAILEY, Id 83333

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Correcting typos and adding front panel referral statement
Product Name: LALGUARD® AZA
EPA Registration Number: 64137-14
Application Date: 03/18/2021
OPP Submission Number: 1066646
OPP Case Number: 00294869

Dear Ms. Roberts:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or

Page 2 of 2

EPA Reg. No. 64137-14

OPP Submission No. 1066646

OPP Case No. 00294869

misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Nina Naimy via email at naimy.nina@epa.gov.

Sincerely,



Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

FAST TRACK label amendment to correct typos and add front panel referral statement

LALGUARD® AZA

A water soluble biopesticide containing 6.0% azadirachtin that is to be injected or applied as a foliar or bark spray to manage insect pests of forests, trees, palms, and landscape ornamentals in woodlot, urban, and residential environments. For non-food use only.

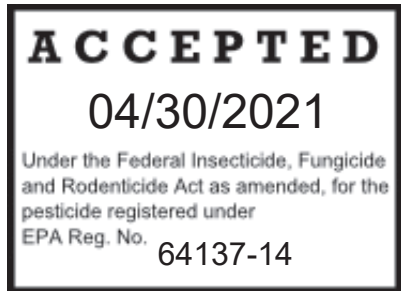
ACTIVE INGREDIENT:

Azadirachtin*6.00%

OTHER INGREDIENTS:..... 94.00%

TOTAL:..... 100.00%

* Contains 0.5 lbs. of Azadirachtin per gallon (60 grams per liter)



KEEP OUT OF REACH OF CHILDREN WARNING

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• 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.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• 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 swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222.	

(See (inner label) (back panel) for additional Precautionary Statements, (First Aid) and Directions for Use)

Net Contents: 0.68 fl. oz. (20 ml), 1.06 quart (1 liter), or 2.12 quarts (2 liter)

EPA Reg. No. 64137-14

EPA Est. 50837-CAN-001

[Batch Number]

Manufactured for:

Danstar Ferment AG/LALLEMAND PLANT CARE
Poststrasse 30
Zug CH-6300 Switzerland

Marketing Company:

Lallemand Inc./BIOFOREST
59 Industrial Park Crescent
Sault Ste. Marie, ON P6B 5P3
Canada

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[Optional marketing claims, may be used on any panel]

- *Pictures illustrating how to determine a trees circumference at working height and performing the injection (i.e. drilling the hole at the proper angle, depth of drill hole and nozzle and canister placement in the tree etc.) may be added.*
- *When injected, provides up to two (2) years protection against emerald ash borer.*
- *Injected directly into the tree for minimal personal, animal and environmental exposure.*
- *Rapid uptake and translocation of LALGUARD AZA after being injected into trees.*
- *Effective control of insect pests that consume tree leaves (e.g. gypsy moth, tent caterpillars, leaf miners), needles (budworms, sawflies), cambial tissue (e.g. Emerald ash borer), shoots (e.g. white pine weevil) and sucking and piercing insects (e.g. scales, Hemlock woolly adelgid).*
- *Trees saving trees*
- *Plant based*
- *Plant based pesticide*
- *Plant based insecticide*
- *Plant based active ingredient*
- *Plant extract*
- *Botanical*
- *Botanical insecticide*
- *Botanical based pesticide*
- *Botanical based active ingredient*
- *Biopesticide*
- *Bioinsecticide*
- *Insecticide*
- *Systemic insecticide*
- *Multiple modes of action*
- *Antifeedant*
- *Insect growth regulator*
- *Repellent*
- *Azadirachtin - Made from seeds of the neem tree*
- *Bio-insecticide from the neem tree "Azadirachta Indica"*
- *Alternative to conventional insecticides*
- *Mix and spray*
- *For indoor and outdoor use*
- *Control on many insects as listed on this label*
- *For use with tree injection equipment*

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if inhaled or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Avoid breathing spray mist. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Waterproof or Chemical resistant gloves
- Protective eyewear

Follow the manufacturer's instructions for cleaning/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:

- Remove clothing/PPE immediately if pesticide gets inside. Then 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.

ENVIRONMENTAL HAZARDS

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 apply when weather conditions favor drift from treated area. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

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 State or Tribal agency responsible for pesticide regulation.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard 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.

Keep children and pets out of the treated area until sprays have dried.

PRODUCT INFORMATION

Inject or apply LALGUARD AZA as a foliar or bark spray to manage insect pests on forests, trees**, palms**, and landscape ornamentals in woodlot, urban, and residential environments. For injections, apply LALGUARD AZA undiluted. For foliar spray applications, apply LALGUARD AZA diluted. Please see the application rate tables below for specific tree injection and foliar spray application directions. Use LALGUARD AZA on a wide variety of plants as listed for indoor and outdoor use.

****USE RESTRICTION: This product is not to be applied to trees that produce edible food and feed.**

MODE OF ACTION

LALGUARD AZA controls target insects on contact or by ingestion. The product affects pests by way of repellence, anti-feeding, interference with the molting process or by disruption egg and gamete formation. Azadirachtin is an insect growth regulator (IGR) that interferes with the synthesis and metabolism of ecdysone and the juvenile hormone. Insects typically die between larval to larval, larval to pupal, nymph to nymph molts, or during adult eclosion. In addition, the product is known to reduce fecundity in both adult female and male insects.

APPLICATION BY TREE MICROINJECTION

This formulation is designed for use with the EcoJect® System for tree injections or with other manufacturers' tree injection devices that meet the label and dosage requirements. Follow the manufacturer's directions for use.

LALGUARD AZA is a systemic insecticide, so to ensure optimum efficacy, it is necessary to inject LALGUARD AZA into the active sapwood. LALGUARD AZA is injected undiluted.

Determining Dose

- Using a diameter tape or calipers, determine the tree's diameter in inches at working height (4.5 ft. above ground).
- Multiply the tree's diameter in inches at working height by appropriate dosage (see Microinjection dose rates in Use Rates table below) to calculate the total dose of LALGUARD AZA for the tree.

Injection Holes

- Using a power drill and a 15/64 in. drill bit for the EcoJect® System (for other injection devices, refer to user instructions for drill bit size), drill a hole at a 20 to 45 degree downward angle into the tree approximately 6-12 in. above ground (high helix drill bits are recommended).
- Extend the hole through the bark approximately ½ -1 in. deep into the sapwood of the tree.

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- Spiral subsequent injection holes slightly upward around the tree every 5-6 in. so the final hole is no more than 11 in. above the ground.

FOLIAR AND LIMB SPRAY APPLICATION RATES FOR ORNAMENTALS AND LANDSCAPE PLANTINGS

To spray LALGUARD AZA, select a suitable power or pump pressure sprayer or a hand-held trigger type sprayer that will deliver a fine spray mist to cover all leaf and limb surfaces. To get complete spray coverage on waxy or hairy plant surfaces, use of an adjuvant is recommended. Do not exceed 8 fl. oz. of LALGUARD AZA per acre.

Spray preparation

For spray applications, apply LALGUARD AZA diluted. Dilute LALGUARD AZA **slowly** into water and agitate to assure uniformity of the spray mixture. Refer to Use Rate Table below on amount of LALGUARD AZA to use. Re-agitate after extended or prolonged standing, as the product will have separated. Prepare only the volume needed for the intended application, and use the spray mixture within 24 hours of preparation.

Mixing instructions

Shake well before mixing. Add LALGUARD AZA concentrate to water **slowly**, with stirring. Using the Use Rates table below, determine the amount of LALGUARD AZA required for the number of acres to be treated and mix with 30 gallons of water per acre. Fill clean spray tank with at least one half the water to be sprayed. Begin agitation and add the determined amount of LALGUARD AZA. Add the remaining water and continue agitation. For uniform distribution on plant canopy and proper dilution, always ensure proper agitation in mixing tanks or vessels.

Always use this product promptly after mixing with water. LALGUARD AZA will break down in the spray solution if not used within 24 hours.

For tank mix compatibility, check with manufacturer. Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures.

Ground equipment

Apply LALGUARD AZA 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.

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. Apply 2 to 3 applications. Spray at an interval of seven (7) to ten (10) days following the rates in the Use Rate Table below when pests are at an immature life stage. Use a spray volume of 30 gallons of water per acre. Refer to Use Rate Table below on amount of LALGUARD AZA to use. 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. Foliar applications should be made to both sides of leaves. The addition of a surfactant, used following the manufacturer's recommendations, may improve product performance. Do not exceed 24 oz. per acre per year of LALGUARD AZA.

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USE RATES FOR PESTS IN TREES AND ORNAMENTALS**

PESTS	SPECIES	MICRO INJECTION DOSE RATES (ml/inch diameter at working height)	FOLIAR SPRAY DOSE RATES PER ACRE (fl. oz.)	FOLIAR SPRAY DOSE RATES PER 10000 sq ft (.25 acre) (fl. oz.)	FOLIAR SPRAY DOSE RATES PER 1000 sq ft (0.02 acre) (fl. oz.)
		Inject LALGUARD AZA undiluted	Spray doses to be diluted in 30 gallons of water per acre		
COLEOPTERA					
Beetles	Including, but not limited to: elm leaf beetle and Japanese beetle	4- 8	5-8	1.3 – 2.0.	0.1-0.2
Emerald ash borer - by injection only.		4- 8	Not applicable		
Weevils	Including, but not limited to: red elm bark weevil, white pine weevil, and beech leaf mining weevil	4- 8	5-8	1.3 – 2.0	0.1-0.2
HEMIPTERA					
Aphids	Including, but not limited to: linden aphid	2.5- 5	5-8	1.3 – 2.0	0.1-0.2
Adelgids	Including, but not limited to: hemlock woolly adelgid	2.5- 5	5-8	1.3 – 2.0	0.1-0.2
Scales	Including, but not limited to: European elm scale, kermes scale, and beech scale	2.5- 5	5-8	1.3 – 2.0	0.1-0.2
HYMENOPTERA					
Sawflies		2- 5	4-8	1-2	0.1-0.2
LEPIDOPTERA					

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Defoliators	Including, but not limited to: gypsy moth, spruce budworm, jackpine budworm, and brown tail moth	2.5- 5	4-8	1-2	0.1-0.2
Leaf miners	Including, but not limited to: arborvitae leaf miners and horse chestnut leaf miner	2.5- 5	4-8	1-2	0.1-0.2
Tent caterpillars		2.5- 5	4-8	1-2	0.1-0.2

NOTE: Low rates are recommended for preventative treatments before signs of insects. **Medium rates** are recommended for most treatments for preventative to medium infestations when pests are present. **High rates** are recommended for difficult to manage pests, heavy infestations, or dense foliage.

APPLICATION BY TREE MICROINJECTION IN PALMS**

For microinjection in palms, dilute LALGUARD AZA to a 3% azadirachtin concentration. Prepare a 3% dilution by combining equal parts product and water in the following order:

1. Prepare required amount of water.
2. Add LALGUARD AZA concentrate to water **slowly**, with stirring.

Use the Use Rates table below to determine appropriate doses for the given canopy sizes.

****USE RESTRICTION: This product is not to be applied to trees that produce edible food and feed.**

USE RATES FOR PESTS IN PALMS**

PALM SIZE	VOLUME OF LALGUARD AZA		VOLUME OF WATER		FINAL VOLUME		INJECTION SITES (MINIMUM)***
	FL. OZ.	ML	FL. OZ.	ML	FL. OZ.	ML	
Small canopy	0.34	10	0.34	10	0.68	20	1
Medium canopy	0.68	20	0.68	20	1.35	40	2
Large canopy	1.02	30	1.02	30	2.03	60	3

***using 20 ml canisters

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place (73 degrees Fahrenheit or less). Avoid overheating and avoid exposure to direct sunlight. Keep container tightly sealed when not in use.

Pesticide 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 Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. 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 Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill.

NOTICE TO USER

Danstar Ferment AG/LALLEMAND PLANT CARE warrants only that this product conforms to the product description on this label and is reasonably fit for the purposes set forth in the Directions for Use when used in accordance with them. However, ineffectiveness or other unintended consequences may result because of such factors as the use, storage or handling of the product contrary to the label instructions, all of which are beyond the control of Danstar Ferment AG/LALLEMAND PLANT CARE. To the extent consistent with applicable law, Danstar Ferment AG/LALLEMAND PLANT CARE shall not be liable for indirect or consequential damages resulting from the use, storage or handling of this product. DANSTAR FERMENT AG/LALLEMAND PLANT CARE MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.