

74779-2

02-19-2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. David Anderson
Rainbow Treecare Scientific Advancements
11571 K-Tel Drive
Minnetonka, MN 55343

FEB 19 2010

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Registrant,

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated September 10, 2009 for:

EPA Registration 74779-2 Bacastat Tree Injection

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington", is written above the typed name.

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---------------------------------------|--|
| 1. Company/Product Number 74779-2 | 2. EPA Product Manager Mary Waller | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Bacastat Tree Injection | PM# 21 | |
| 5. Name and Address of Applicant (Include ZIP Code) Rainbow Treecare Scientific Advancements 11571 K-Tel Drive Minnetonka, MN 55343 <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 checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. NOTIFICATION |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. FEB 19 2010 |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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.

Section - III

| | | | | | |
|---|--|---|---|---|-------------------|
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. 2.94 grams | No. per container 20 | 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 58.8 grams | | 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 David L. Anderson | | Title Director of Regulatory Affairs | |
| | | Telephone No. (Include Area Code) 952-252-0541 | |
| 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 Director of Regulatory Affairs | |
| 4. Typed Name David L. Anderson | | 5. Date September 9, 2009 | |



September 10, 2009

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504P)
Registration Division
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive (South Building)
Arlington, VA 22202

ATTENTION: Mary Waller
Product Manager, Team 21

SUBJECT: Rainbow Treecare Scientific Advancements
Bacastat Tree Injection
(EPA Reg. No. 74779-2)
Notification

Dear Ms. Waller:

Rainbow Treecare Scientific Advancements is submitting a notification to update the Storage and Disposal statement for our Bacastat Tree Injection (EPA Reg. No. 74779-2) per PR Notice 2007-4.

I am submitting one (1) clean copy of draft labeling for your review and acceptance. If you have any questions, please contact me either by phone at 952-252-0541 or by email at danderson@treecarescience.com.

Sincerely,

A handwritten signature in black ink, appearing to read "David Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

David Anderson
Director of Regulatory Affairs
Rainbow Treecare Scientific Advancements
11571 K-Tel Drive
Minnetonka, MN 55343

Enclosures:

www.treecarescience.com

11571 K-Tel Drive Minnetonka, MN 55343 office 952.922-3810 fax 952.252-0504

Scientifically Proven Products with Predictable Results

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Bacastat™ Tree Injection

FEB 19 2010

Bacastat™ Tree Injection is a unique water soluble oxytetracycline formulation that is used for injection into non-crop bearing ornamental trees such as oak, elm, sycamore, and palm for suppression of bacterial diseases. Bacastat is tree friendly, as it contains no solvents.

Contents will treat 100 trunk diameter inches (DBH).

| | |
|--------------------------------|---------|
| Active Ingredient | |
| Oxytetracycline Hydrochloride* | 18.30% |
| Related compounds | 0.17% |
| Other Ingredients | 81.53% |
| Total | 100.00% |

*Equivalent to 17% oxytetracycline

KEEP OUT OF REACH OF CHILDREN CAUTION

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

See Side/Back Panel for Additional Precautionary Statements, First Aid and Directions for Use

EPA Reg. No. 74779-2

EPA Est. No. 74779-MN-1

Net Contents: 58.8g (2.07 oz) (20 individual 2.94g or 0.104 oz packets)

Rainbow Treecare Scientific Advancements

11571 K-Tel Drive

Minnetonka, MN 55343

1-877-ARBORIST

1-877-272-6747

www.treecarescience.com

| 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 eye.• 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. |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. | |

HOT LINE NUMBER

For 24-hour medical emergency assistance (human or animal), or chemical emergency assistance (spill, leak or accident), Call CHEMTREC at 1800-424-9300

PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Harmful if absorbed through skin. Do not breathe mist. Prolonged or frequently repeated exposure may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or the toilet. Remove and wash contaminated clothing before reuse. This material is not to be used for medical veterinary or human purposes.

Personal Protective Equipment (PPE)

Some materials that are chemical resistant to this product are listed below. If you want more options, follow the instructions for Category A on an EPA chemical resistant category selection chart.

Applicators and other handlers must wear:

- Long sleeved shirt
- Long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

User Safety Requirements:

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:

Users must:

- 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

Do not apply directly to water, 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.

Restrictions

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. Do not apply this product through any type of irrigation system. Only use **Bacastat™ Tree Injection** on trees greater than 6" in diameter. To be used on non-crop bearing ornamentals only.

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 apply to uses that are covered by the Worker Protection Standard.

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

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, wear:

- Coveralls over long-sleeved shirts and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

Resistance Management Statements **Bacastat™ Tree Injection** contains a Group 18 (fungicide/bactericide). Fungal isolates/bacterial strains with acquired resistance to Group 18 may eventually dominate the fungal/bacterial population if Group 18 fungicides/bactericides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by **Bacastat™ Tree Injection** or other Group 18 products.

To delay fungicide/bactericide resistance consider:

- Avoiding the consecutive use of **Bacastat™ Tree Injection** or other target site of action Group 18 fungicides/bactericides that have a similar target site of action, on the same pathogens.
- Using tank-mixtures or premixes with fungicide/bactericides from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or pre-pack rate on the pathogen(s) of concern. Do not use any product that has a prohibition on tank mixing and follow the more restrictive use directions.
- Basing fungicide/bactericide use on a comprehensive IPM program.
- Monitoring treated fungal/bacterial populations for loss of field efficacy.
- Contacting your local extension specialist, certified crop advisors, and/or manufacturer for fungicide/bactericide resistance management and/or IPM recommendations for specific crops and resistant pathogens.

Bacterial Leaf Scorch

Apply once per growing season using a micro injection or macro infusion system. Make treatments after full leaf development in the spring and prior to July 1st for best effectiveness. Treatment with **Bacastat™ Tree Injection** suppresses scorch symptoms only in the year of treatment. Re-treatment is required each

growing season for continued suppression of scorch symptoms. Using this product in combination with sound cultural treatments such as mulching, irrigation during periods of drought, and management of insect and disease pests is helpful in suppressing symptoms and delaying the onset of decline.

The Growth Regulator **Cambistat™** has been shown to be effective in suppressing Bacterial Leaf Scorch symptoms by increasing the drought tolerance and improving the vigor of infected oak trees.

Lethal Palm Yellows

Apply every 3 months for suppression of symptoms on palm trees. It is not recommended that this program be carried out indefinitely. A replanting program that utilizes native palms that are resistant to Lethal Yellows must accompany treatment.

Application Methods

Root Flare Injection

Bacastat™ Tree Injection can be used with a variety of root-flare injection devices including small volume microinjection and high volume macro-infusion devices. For all injection devices, read carefully and follow all manufacturer use directions.

Most injection devices may require several minutes or more to empty into the tree, however, some may take longer to empty depending on the health of the treated tree and local weather conditions. Do not leave the injection devices unattended and promptly and safely remove them, according to the manufacturer's recommendations. Do not leave empty injection devices on trees. Follow the manufacturer's recommendations for proper cleaning and storage of the injection devices.

If the injection device does not completely empty within a few hours, depressurize the device and remove from the tree in an inverted position to avoid the solution leaking. When using a refillable injection device, empty the leftover solution into an enclosed chemical resistant container. After the leftover solution has been emptied from the injection device, triple rinse the device with water. Ensure that the rinsate is collected in an enclosed chemical resistant container. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Micro-Injection (Small Volume Devices):

Mixing Instructions

1. Measure the diameter of the tree at breast height (DBH).
2. Use 1 package of **Bacastat™ Tree Injection** for each 5" diameter (or 16" Circumference).
3. In a separate chemical resistant container, combine 45 ml (1.5 fl. oz.) of water for every 1 package of **Bacastat Tree Injection**. Place the package in the container unopened (the packaging will dissolve).
4. Seal the container and gently shake the solution until the **Bacastat™ Tree Injection** has dissolved and the contents are evenly distributed throughout the mixture. Mix only the desired amount of **Bacastat™ Tree Injection** that will be used for each application and use immediately after adding water.
5. Dispense 9 milliliters (0.3 fl. oz.) of ready to use solution per inch of tree diameter into each individual injection device. For best tree distribution use approximately 1 injection site for every 2" diameter inches (approximately 1 injection site every 6 inches) evenly spaced around the root-flares.

Installation and Application using the Rainbow Treecare Scientific Advancement M3 infuser:

1. Examine the tree for the presence of root flare. If flares are not visible, excavate the root collar.
2. Thoroughly brush all dirt from the root flare. A dirty root flare will dull the drill bit and increase Bacastat uptake time.

3. Close the M3 infuser control valve.
4. Attach the mixing bottle to the M3 fill gun.
5. Insert the needle of the M3 fill gun into the M3 infuser duckbill valve and inject up to 18 mls (0.6 fl. oz.) of treatment solution. Note: Do not penetrate the duckbill valve with the needle.
6. Lay the M3 infusers around the tree to select injection sites. The application rate is 1 injection site for every 2 diameter inches (approximately 1 injection site every 6 inches). Evenly space the M3 infusers around the root-flares. Using a 15/64" HIGH HELIX drill bit, drill a hole at a downward angle into each selected buttress root flare above the soil line. Drill to a depth of 3/4 to 1 inch (2 to 2.5 cm) past the bark into healthy xylem tissue. The hole needs to be drilled at an angle that will allow the M3 infuser to empty. If the M3 infuser is too horizontal to the ground, the solution may not completely drain and will remain inside the infuser.
7. Insert the injector tip of the M3 infuser into the hole and seat firmly with hand pressure.
8. Start the infusion. Holding the M3 infuser firmly with one hand, turn the control valve to the left (Counter-clockwise) until fluid has entered the tip. If you find that the solution is not emptying, air may be added to increase the internal pressure within the M3 infuser. Insert the fill tip of the M3 charger into the duckbill inject up to 10 – 15 cc of air.
9. Check for leaks. If leaks are found close the valve, seat firmly into the tree and re-open the valve. If leaks persist, the problem may be too shallow of a hole. Close the valve, remove the infuser and re-drill to a deeper depth.
10. Uptake usually occurs within minutes. When all of the treatment liquid is out of the injector, a wash solution of water can be injected into the M3 injector and it can be re-pressurized or the M3 injector can be closed and removed from the tree.
11. Remove the M3 injector from the tree and store properly for reuse.

Macro-Injection (Large Volume System):

With this product, a 3 –5 gallon hand pump reservoir is the recommended device along with the Rainbow Scientific Tee and Harness system.

Mixing Instructions

1. Measure the diameter of the tree at breast height (DBH).
2. Use 1 package of **Bacastat™ Tree Injection** for each 5" diameter (or 16" Circumference).
3. In your hand pump reservoir, combine 750 ml (25.5 fl. oz.) of water for every 1 package of **Bacastat™ Tree Injection**. With large volume systems, more water can be utilized without a decrease in product effectiveness. Place the water soluble packet in the container unopened (the packaging will dissolve).
4. Seal the container and gently shake the solution until the **Bacastat™ Tree Injection** has dissolved and the contents are evenly distributed throughout the mixture. Mix only the desired amount of **Bacastat™ Tree Injection** that will be used for each application and use immediately after adding water.

Installation and Application:

1. Examine the tree for the presence of root flare. If flares are not visible, carefully remove soil from the base of the tree to uncover the top of the flare roots. Brush away loose soil. Very thoroughly – Dirty flares will dull the drill bit and increase uptake time. Make infusion sites 4-8 inches below the top of the root flare.
2. Drill holes through the bark, into sapwood, using a clean, sharp, HIGH HELIX drill bit. Drill perpendicular to the surface of the flare. Drill hole diameter needs to be adequate to allow insertion of injection tees and formation of airtight contact between active xylem and the delivery point of the injection tees. When using the Rainbow Scientific tees, use a 15/64-diameter drill bit. Follow manufacturer's instructions if other injection devices are used in the treatment.

Drill hole depth must be adequate to deliver the product into active xylem tissue. Make the depth approximately 1 inch past the bark. Drill at slow speeds and do not unnecessarily spin the bit in the hole.

For best tree distribution use 1 injection site for every 2 diameter inches (approximately 1 injection site every 6 inches) evenly spaced around the root-flares.

3. Check each tee to be sure it is not plugged and replace badly damaged tees. Firmly insert tees by hand. Attach tubing from the solution reservoir to feed into the harness in 2 locations, on opposite sides of the tree.
4. Pull out 2 tees on opposite sides of the tree. Prime the pump if it is not self-priming. Turn on the pump and bleed the air out of the line. With all air out of harness, re-insert the 2 tees and check for leaks. Adjust the pressure to 15-20 psi. Lightly tap any leaking tees.
5. During the infusion, monitor tees for leaks. Maintain pressure at 15-20 psi.
6. Turn off the pump when air is drawn into the harness. Remove tees from the tree. Flush holes with water to assist with wound closure. Replace soil and sod around the base of the tree. It is not necessary to treat drill holes with wound paint or other sealing compounds.

STORAGE AND DISPOSAL

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

Pesticide Storage: Keep tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (<77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature. If the injection device does not completely empty within a few hours, depressurize the device and remove from the tree in an inverted position to avoid the solution leaking. When using a refillable injection device, empty the leftover solution into an enclosed chemical resistant container which is labeled with the product name and EPA registration number.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

Notice: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Tree injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or tree conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS or seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS and seller harmless for any claims relating to such factors.

RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions. This warranty does not extend to the use of the product contrary to label instructions, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, RAINBOW TREECARE MAKES NO WARRANTIES OR MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the fullest extent permitted by law, RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE

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EXCLUSIVE REMEDY OF THE USER OR BUYER, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF RAINBOW TREECARE OR SELLER, THE REPLACEMENT OF THE PRODUCT.

RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS and Seller offer this product, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS.

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OPTIONAL MARKETING CLAIMS

Aids in the suppression [control] of Ash Yellows

Aids in the suppression [control] of Bacterial Leaf Scorch (&) (Phloem Necrosis) of Elm

Aids in the suppression [control] of Bacterial Leaf Scorch of Oak

Aids in the suppression [control] of Palm Lethal yellows

Aids in the suppression [control] of Bacterial Blight of flowering crabapple (hawthorn)

Aids in the suppression [control] of Bacterial canker of hickory [horsechestnut], [maple], [mimosa], [oak], [walnut]

Aids in the suppression [control] of Fire Blight of ornamental [apple] [cherry] [crabapple] [hawthorn] [mountain ash] [pear]

Aids in the suppression [control] of Vascular Yellows of ash (elm)

Aids in the suppression [control] of fungal and bacterial pathogens systemically

For seasonal suppression [control] of certain diseases of ornamental trees

Suppresses [controls] certain diseases of ornamental trees

Contents [117.6g] [176.4g] will treat [200] [300] trunk diameter inches (DBH).