



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 4, 2024

Kim Davis
Consultant to Bio-Care Technology Pty. Ltd.
RegWest Company, LLC
9017 18th Street
Greeley, CO 80634

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 -- to correct the name of the active ingredient on page four in the "Product Information" section
Product Name: NOGALL
EPA Registration Number: 93445-1
EPA Receipt Date: 04/11/2024
Action Case Number: 00606608

Dear Ms. Davis:

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

The U.S. Environmental Protection Agency (EPA) is in receipt of your applications for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced products. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of these requests for applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

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. 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 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 statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions, please contact Michael Glikes by phone at (202) 566-1461 or via email at glikes.michael@epa.gov.

Sincerely,



Digitally signed by
ALAN REYNOLDS
Date: 2024.06.07
11:38:48 -04'00'

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

NOGALL®

{Box Label-Front Panel}

NOGALL®

Biological Pesticide

For Biological Control of Crown Gall Disease
For Use on Only Non-Food or Non-Food Bearing Plants

Active Ingredient:

Rhizobium rhizogenes strain K1026* 0.03%

Other Ingredients 99.97%

Total 100.00%

*Contains not less than 1×10^9 colony-forming units (cfu) per gram of moist peat medium. When mixed as directed, it will provide a suspension of not less than 2.64×10^7 cfu per milliliter of the dip solution.

EPA Reg. No. 93445-1

EPA Est. 93445-AUS-1

KEEP OUT OF REACH OF CHILDREN CAUTION/PRECAUCIÓN

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 booklet for complete First Aid, Precautionary Statements,
Directions for Use and Conditions of Sale and Warranty.

You may contact Poison Control for emergency medical treatment information at 1-800-222-1222.

Net Weight: 8.8 oz (250 g)



{Box Label-Back Panel}

BOOKLET ATTACHED HERE

{Box Label-Side Panels}

NOTIFICATION

93445-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

06/07/2024

Manufactured by:

Bio-Care Technology Pty. Ltd.
248 Tyagarah Road
Myocum, NSW 2481 Australia

Distributed in the U.S. for

Bio-Care Technology Pty. Ltd. by:
Evergreen Growers Supply, LLC
15875 SE 114th Avenue, Building 1 Suite G
Clackamas, OR 97015

UPC {Barcode No. 7 96548 44424 5}

Batch Number: _____
Not for Sale or Use After: _____

NOGALL is a registered trademark of Bio-Care Technology Pty. Ltd.

{Booklet}

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For Biological Control of Crown Gall Disease
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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.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Poison Control for emergency medical treatment information: 1-800-222-1222.	

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

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

Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R or P filter; OR a NIOSH-approved powered air purifying respirator with an HE filter. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are given, 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

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 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 State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and restricted-entry interval (REI). The requirements in this box only apply to uses of this product 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 **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
- shoes plus socks
- waterproof gloves

In case of medical emergency regarding this product, call:

- Your local doctor for immediate treatment
- Your local poison control center (hospital)
- Poison Control 1-800-222-1222

Product Information

NOGALL® is a living culture that must be protected against sunlight and temperature extremes. **DO NOT** use with any fertilizers, chemicals or other pesticides that may harm the bacteria. Mix only with clean, chlorine-free water, using clean containers and utensils. **DO NOT** wash treated stock prior to planting. **NOGALL** is used to dip or spray (inoculate) germinating seeds, roots and stems, and cuttings of non-food (gall free) or non-food bearing (gall free) almond, apricot, caneberry, cherry, euonymus, nectarine, peach, pecan, plum, rose and walnut. Plant material should be inoculated at each transfer stage, if possible.

NOGALL helps protect infection sites against the crown gall disease organism (*Agrobacterium tumefaciens*) and should be used when highly susceptible plant material is transferred and/or subjected to wounding, such as when taking cuttings, germinating seeds, re-potting, field lifting and replanting, etc. Successful control of crown gall disease in the above hosts is largely due to the production of the antibiotic agrocin 84 and root colonization by *Rhizobium rhizogenes* ~~*Agrobacterium radiobacter*~~ strain K1026 contained in **NOGALL**. Control of sensitive pathogenic agrobacteria is most effective with correctly applied **NOGALL**. Where pathogenic bacteria are resistant to agrocin 84, however, then control can be considerably reduced.

NOGALL is shipped in packs of 8.8 ounces (250 g) of concentrated, moist peat bacterial cultures.

Use Limitations

Chemigation: DO NOT apply this product through any type of irrigation system.

Application Instructions

Germinating Seed Application to almond, apricot, cherry, nectarine, peach, pecan, plum and walnut: Dip 37.5 pounds of seed into a suspension of **NOGALL** prepared by adding 8.8 oz of **NOGALL** to 2.5 gallons of clear, unchlorinated water in a clean container. The surface of the seed must be thoroughly wet. Remove the seed from the suspension, drain off excess liquid and sow immediately. **DO NOT ALLOW THE SEED TO COMPLETELY DRY BEFORE SOWING.**

Root and Stem Application to non-food bearing almond, apricot, caneberry, cherry, nectarine, peach, pecan, plum and walnut and non-food euonymus and rose: Treat seedlings of stone fruit trees, nut trees, spindle trees and roses with **NOGALL** within 2 hours of lifting, root pruning or other handling operations that damage plant tissue and before and after cold storage. Dip or spray bare rootstock with **NOGALL** suspension (8.8 oz of **NOGALL** to 2.5 gallons of clear, unchlorinated water) until root surfaces and the stem above the bud or graft union are completely wet, or spray these tissues to runoff. Replace treatment suspension after treating the equivalent of 1,000 plants/gallon of suspension or sooner when larger trees are dipped or when the suspension becomes excessively dirty. Larger plants may require 10-15 gallons of suspension per 5,000 plants. Protect treated plants from direct sunlight and excessive drying by storing in a cool, humid area or heeled-in clean, moist material such as sphagnum or sawdust. Treated plants must be protected from drying during transport to the planting site and during the planting operation.

Cutting Application to non-food bearing almond, apricot, caneberry, cherry, nectarine, peach, pecan, plum and walnut and non-food euonymus and rose: Treat cuttings by dipping clean basal ends in a suspension of **NOGALL** prepared by adding 8.8 oz of **NOGALL** to 2.5 gallons of clear, unchlorinated water in a clean container. Treated cuttings must be protected from drying and direct sunlight by storing in a cool, humid area until they are placed in rooting media. When using alcohol-based rooting compounds, dip cuttings in accordance with directions, allow to dry for 2 hours and then treat with **NOGALL**. Treat cuttings with **NOGALL** before and after cold storage.

Mixing Instructions

Stir vigorously and periodically stir solution during use. An 8.8 oz (250 g) pack properly mixed in water will treat 2,500 bare root seedlings (1/4 inch caliper). **Do not hold diluted suspension for more than 8 hours.**

STORAGE AND DISPOSAL

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

Pesticide Storage: Store at refrigeration temperature (35-40°F) and use before the date stamped on the side panel of this box. **DO NOT** store cartons where they can be punctured or crushed by sharp or heavy objects. **DO NOT** store part of an opened packet as it may deteriorate through contamination. Store **NOGALL**® separate from other pesticides, fertilizer, food and feed to prevent cross contamination. Maximum period of storage is 6 months from the date of manufacture. The expiration date is printed on the side panel of this box. If the foil or plastic pouch in the carton is ruptured accidentally or spilled, sweep the spilled contents into a dust pan, place the contents in a tied plastic bag and discard in the garbage. Rinse the area of the spill with several rinses of water.

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

Container Handling: Nonrefillable container. DO NOT reuse or refill this container. Completely empty foil or plastic pouch by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, offer for recycling if available or dispose of empty foil or plastic pouch in a sanitary landfill, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If outer carton is contaminated, dispose of it in the same manner as required for the foil or plastic pouch.

Conditions of Sale and Warranty

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as use on infected stock, the presence of other or untested or unapproved materials, seed of low quality or low vigor or low germination, use of the product in a manner inconsistent with its labeling, misapplication of this product, or weather conditions at planting or environmental conditions during seed storage, all of which are beyond the control of BIO-CARE TECHNOLOGY PTY. LTD. ("BIO-CARE") or the Seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

BIO-CARE warrants that this product conforms to the description on the label and is reasonably fit for the purposes referred to in the **Directions for Use**, subject to the inherent risks, referred to above.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BIO-CARE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY,

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S EXCLUSIVE REMEDY AND BIO-CARE'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THIS PRODUCT.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BIO-CARE AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, EXEMPLARY, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

BIO-CARE and the Seller offer this product, and the Buyer and User accept it, subject to the foregoing **Conditions of Sale and Warranty** that may be varied only by agreement in writing signed by a duly authorized representative of BIO-CARE.

{Culture Bag (40 mm) and Box (30 mm) Labels}

EPA Reg. No. 93445-1

EPA Est. 93445-AUS-1

BC1409

K1026

[{Year}]

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market label