

PM 92

62388-1

9/28/99

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511W)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

62388-1

SEP 28 1999

Term of Issuance: Conditional

Name of Pesticide Product:

NOGALL

NOTICE OF PESTICIDE:

[x] Registration

___ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ms. Amy Roberts (U.S. Agent)
Technology Sciences Group Inc.
1101 17th Street, N.W.
Suite 500
Washington D.C. 20036-4704

FOR: Mr. Gary Bullard
Bio-Care Technology Pty Limited
RMB 1084 Pacific Highway
Somersby, NSW 2250
AUSTRALIA

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

- 1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This registration is registered under FIFRA § 3(c)(7)(C) because of the following outstanding data described below.

A. Repeat the growth temperature studies to determine the maximum growth temperature of Agrobacterium radiobacter strain K1026. Bio-Care must measure the growth temperature of the incubators (or growth chamber etc.) with a calibrated measuring device accurate to 0.1 to 0.2°C several times per day (at least three to four) for several days to assure the accuracy of growth temperature measurements. Two-degree temperature intervals beginning at 29°C and up to and including 37°C should be used. Bio-Care must submit an appropriate protocol for EPA review before initiating the study. Survival at human body temperature would raise the possible hazard to humans that K1026 might be an opportunistic pathogen. This condition must be satisfied within one year of the conditional registration date.

Continued...

Signature of Approving Official:

[Handwritten signature]

Date:

9-28-99

CONCURRENCES

Table with columns for SYMBOL, SURNAME, DATE and rows for 7511C, Mathew, 9/27/99 and 7511C, [Signature], 9/28/99

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B. Repeat the following substrate utilization studies, using both K84 and K1026, where the results differed between the two strains in previously submitted study MRID No. 447943-01: ribose, cellobiose, melibiose, xylitol, B-gentiobiose, D-turanose, D- and L-fucose. Bio-Care must submit an appropriate protocol for EPA review before initiating the study. These data will facilitate the determination of the lineage of K1026. Pending the results of these studies, additional non-target species or environmental fate data may be required by the Agency. This condition must be satisfied within one year of the conditional registration date.

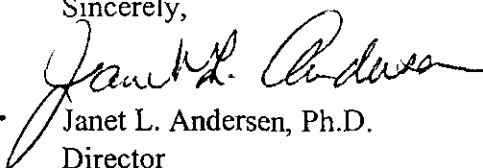
4. This registration will automatically expire on midnight September 30, 2001. EPA will reevaluate the potential for *Agrobacterium radiobacter* strain K1026 to survive at human body temperatures and the relatedness of K1026 and K84 before deciding on whether to convert the registration to a non-expiring registration.

5. Submit five(5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division (7511C)

cc: Encl.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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NOGALL

for

Biological Control of Crown Gall

FOR USE ON NON-FOOD AND NON-BEARING PLANTS ONLY

ACTIVE INGREDIENT:*Agrobacterium radiobacter* (strain K1026) 0.25%
 OTHER INGREDIENTS: 99.75%
 TOTAL: 100.00%
 Contains not less than 1,000 million 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 in the dip solution.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID

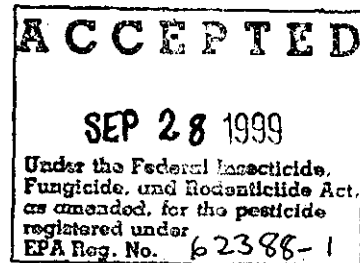
If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

EPA REGISTRATION No. (File Symbol 62388-R)
 EPA ESTABLISHMENT No. 62388-AU-001
 US PATENT NO. 5,354,684

Manufactured by:
 Bio-Care Technology Pty Ltd
 RMB 1084 Pacific Highway
 Somersby NSW 2250
 Australia
 Int'l Ph: 61 2 4340 2246

Net Contents: XX



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.

Personal Protective Equipment (PPE):

Applicators and other handlers must wear long sleeved shirt and long pants, waterproof gloves, and shoes plus socks. As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

User Safety Requirements:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove PPE immediately after handling this product. If gloves are worn, 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, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

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 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 for exceptions pertaining to the statements in this labeling about PPE, restricted-entry intervals, and notification to workers. 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 long-sleeved shirt and long pants, shoes plus socks and waterproof gloves.

CHEMIGATION

Do not apply this product through any type of irrigation system.

GENERAL INSTRUCTIONS & INFORMATION

4085
NOGALL is a living culture that must be protected against sunlight and extremes of temperature. Do not use with any other pesticides, fertilizers or chemicals 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 or roots and stems of non-bearing, gall-free cherry, peach, nectarine, apricot, plum, almond, walnut, pecan, caneberry, euonymus and rose stock. 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 *Agrobacterium radiobacter*, strain K1026, contained in NOGALL. Control of sensitive pathogenic agrobacteria is most effective with correctly applied NOGALL but where pathogenic bacteria are resistant to agrocin 84 then control can be considerably reduced.

APPLICATION INSTRUCTIONS

CROP: Germinating Seed Application to seeds of almond, apricot, cherry, nectarine, peach, plum, walnut, and pecan: Dip 15 pounds of seed into a suspension of NOGALL prepared by adding 100g of NOGALL to 1 gallon 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. DO NOT HOLD DILUTED SUSPENSION FOR MORE THAN 8 HOURS.

CROP: Root and Stem Application to non-bearing almond, pecan, apricot, caneberry, cherry, nectarine, peach, plum, walnut and ornamentals such as euonymus and rose: Seedlings of stone fruit trees, nut trees and roses should be treated with NOGALL within 2 hours of lifting, root pruning or other handling operations that damage plant tissue and before and after cold storage. Bare rootstock should be dipped or sprayed with NOGALL solution until all 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 1000 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. Treated plants should be protected 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.

CROP: Cutting Application to cuttings of almond, pecan, apricot, caneberry, cherry, nectarine, peach, plum, walnut and ornamentals such as euonymus and rose: Cuttings are treated by dipping clean basal ends in NOGALL suspension. Use 100g per gallon of water as described above. 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.

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MIXING DIRECTIONS

NOGALL is shipped as packs of either 100 grams or 500 grams of concentrated, moist peat bacterial cultures. There are at least 1,000 million cfu of *A. radiobacter*, strain K 1026, per gram of product.

Stir vigorously and periodically stir solution during use. A 100 gram or 500 gram pack properly mixed in water will treat 1,000 or 5,000 bare root seedlings (1/4 inch caliper), respectively. DO NOT HOLD DILUTED SUSPENSION FOR MORE THAN 8 HOURS.

STORAGE & 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 expiration date. 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, fertilizers, food and feed to prevent cross contamination. Maximum period of storage is 6 months.

Pesticide Disposal: If the bag is ruptured accidentally or spilled, sweep the spilled contents into a dustpan, place the contents in a tied plastic bag and discard in the garbage. Rinse the area of the spill with several rinses of water.

Container Disposal: Dispose of carton and empty bag in a sanitary landfill, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

WARRANTY STATEMENT

Bio-Care Technology Pty Limited ("Bio-Care") warrants that NOGALL conforms to the biological specifications for the product which are set forth on this label and is reasonably fit for the purposes described in the directions for use when used in strict accordance with the directions for use and other instructions set forth on this label. Lack of performance or other intended consequences may result because of such factors as use of the product contrary to directions for use, abnormal conditions (such as storage of product; improper dilution and mixing; over exposure of treated plant materials to sun, heat and wind; poor timing of treatment), presence of other materials, the manner of application or other factors, all of which are beyond the control of Bio-Care, New BioProducts, Inc., or the seller.

All such risks shall be assumed by the buyer. BIO-CARE'S SOLE LIABILITY AND OBLIGATION CONCERNING NOGALL WILL BE TO REPLACE ANY OF THE PRODUCT WHICH DID NOT CONFORM WITH THE AFORESAID BIOLOGICAL SPECIFICATIONS AT THE TIME OF DELIVERY AND WHICH IS REPORTED TO NEW BIOPRODUCTS, INC. WITHIN 30 DAYS OF THE DATE OF DELIVERY TO THE CUSTOMER. THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL BIO-CARE OR NEW BIOPRODUCTS, INC. BE LIABLE FOR LOSS OF PROFIT OR GOODWILL OR OTHER SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES SUFFERED BY BUYER OR ANY OTHER PARTY AS A RESULT OF THE USE OF NOGALL BY BUYER OR ANY OTHER PARTY. THE EXCLUSIVE REMEDY OF BUYER OR ANY OTHER PARTY USING NOGALL IS THE REPLACEMENT OF NON-CONFORMING PRODUCT BY BIO-CARE AS SET FORTH ABOVE.

This limited warranty shall be governed by and construed in accordance with the laws of the State of Oregon.

DISTRIBUTED BY:

New BioProducts Inc,
2166 NW Fritz Place
Corvallis, OR, 97330
Ph: (541) 752-2045, Fax: (541) 754-3968