

40230-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823

Subject: AgBioChem, Inc., Galltrol-A
EPA Registration No. 40230-1
Label Amendment ("Fast Track")
Application Dated: 03/05/09

MAY 27 2009

Dear Mr. Messerschmidt:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1. Updated first aid, precautionary, WPS and PPE statements;
- 2. Simplified Use Directions (no changes to rates, timing or crop sites); and
- 3. Revised warranty statement.

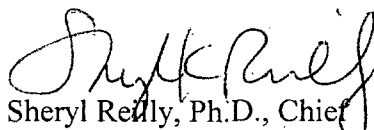
The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

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 bearing the amended labeling constitutes acceptance of these conditions. If you have any questions please contact Anna Gross at 703-305-5614 or by email at: gross.anna@epa.gov.

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

Sincerely,


 Sheryl Reilly, Ph.D., Chief
 Microbial Pesticides Branch
 Biopesticides and Pollution
 Prevention Division (7511P)

Enclosures (2)

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	GROSS	Reynolds	Reilly					
DATE	5/26/09	5/26/09	5/27/09					

GALLTROL – A

BIOLOGICAL PREVENTION OF CROWN GALL DISEASE

Bacterial inoculant which aids the control and prevention of crown gall on certain fruit, nut and ornamental nursery stock (including bare-root seedlings, liners and planting stock)

ACTIVE INGREDIENT: *Agrobacterium radiobacter* (Strain 84).....99.00%
1.2 x 10¹¹ c.f.u./plate* (Equivalent to 1 liter of 1.2 x 10⁸ cells per ml.)

INERT INGREDIENTS: occluded H₂O.....1.00%
100.00%

*Each culture plate 150 mm (6 inches) in diameter contains 50 ml. of agar culture medium and has a surface of 17,663 sq. mm. or 28 sq. in. containing not less than 1.2 x 10¹¹ colony forming units of bacteria as a surface growth. Agar is not used – discard after removal of bacteria.

Keep out of Reach of Children
CAUTION – AVISO

FIRST AID	
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)	
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.
<ul style="list-style-type: none"> • Have the product container or label with you when calling a poison control center or doctor or going for treatment. • For emergency information on Galltrol-A, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222. 	

EPA Reg. No. 40230-1
EPA Est. No. 040230-CA-001
Net weight (a.i.): 0.35 oz.
Patent Pending

LOT No.
Date Mfrd.
Perishable use

Manufactured in U.S.A. by
AgBioChem, Inc.
3 Fleetwood Court
Orinda, CA 94563
(530) 586-1561
www.agbiochem.com

ACCEPTED

MAY 27 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 40230-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. 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 pants
- Shoes plus socks
- Protective eyewear

Follow manufacturer's instructions for cleaning and 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

- User should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- User should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and clean into clean clothing.

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.

Environmental Hazards: Do not apply 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 the labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide application.

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), notification to workers, and restricted-entry interval. The requirements in this box 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 12 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
- protective eyewear
- socks and shoes

Use Precautions

- Keep GALLTROL refrigerated (35°- 40°F). Use as soon after receipt as possible; do not use after 120 days. Do not use if frozen or allowed to get hot or dry.
- When preparing dip or spray suspensions of GALLTROL, use clean containers and nonchlorinated water free of copper, zinc or bactericidal materials to avoid loss of potency.
- GALLTROL bacteria may be inactivated by freezing or by exposure to high temperatures, sunlight and desiccation. Do not expose plates to sunlight. GALLTROL bacteria do not survive well from day to day in water. Mix fresh suspension of GALLTROL each day.
- Crown gall infections occur through fresh plant wounds. Dip or spray treated stock the same day that wounding (e.g., cutting, lifting, digging, root pruning, handling) or planting occurs.
- After application, do not wash or remove the bacterial suspension from plants. Pre-existing gall infection is not controlled by GALLTROL.

APPLICATION DIRECTIONS

For use only on the seeds, roots or stems of certain plants susceptible to crown gall infection:

Use Sites (Terrestrial and Greenhouse Non-food Crops)	
Non-Bearing Fruit and Nut Nursery Stock	Ornamental Nursery Stock
almond, apple, apricot, blueberry, caneberries (blackberry, boysenberry, raspberry, youngberry), cherry, grape, kiwifruit, nectarine, peach, pear, pecan, plum, prune, walnut	Euonymus, rose, weeping cherry, willow, poplar, clematis, etc.

(Note: resistant strains of crown gall bacteria may be found.)

GALLTROL is used at the rate of bacteria from 1 plate per gallon of water (nonchlorinated). Remove the mass of bacteria from the agar surface by submerging plate in water and gently wiping with gloved hand. Mix bacteria with water in a clean bucket for dip or hand spray. Rinse the plate free of bacteria and use immediately. Discard dish and agar. Plants should be treated within 12 hours after each event causing new wounds. Wash roots clean and prune broken roots, if possible, before treating. Prepare new GALLTROL suspension whenever it becomes excessively dirty. Discard prepared solution after 24 hours. To spray, use small hand-operated sprayer producing coarse spray with large droplets.

Germinating Seed Application (Non-bearing Fruit and Nut Trees): Apply by dipping seed in GALLTROL immediately prior to planting in seed bed.

Cutting Application: Dip or hand spray clean basal ends in GALLTROL mix. Treat before and after cold storage, when possible.

Root and Stem Application: Bare-root stock should be dipped or thoroughly sprayed (saturated) with GALLTROL suspension to cover roots and stem up to bud or graft union. One gallon of GALLTROL mix may treat following numbers of trees of specified caliper size: 200 trees @ ¾"-1"; 300 trees @ 5/8"; 400 trees @ ½"; and 800 trees @ ¼". Amount of GALLTROL mix required will vary depending on size of root ball and treatment method. Treat within 12 hours after lifting (digging) from nursery or causing any other wounding event, and on the same day as planting.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store GALLTROL-A containers closed in a plastic bag under refrigeration (35°- 40° F) until ready for use. Use as soon after receipt as possible. Do not use after 120 days of receipt. GALLTROL-A bacteria may be inactivated by freezing or by exposure to high temperature, sunlight and desiccation. Do not expose plates to sunlight.

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

Container Disposal: Securely wrap petri dishes and packaging in newspaper and dispose of these in a sanitary landfill, or by incineration. Do not burn. GALLTROL agar culture media are depleted and inactive after use. The unsterile agar media and plates should be disposed of through normal channels for non-toxic, non-burnable household wastes.

DO NOT REPACKAGE GALLTROL.

WARRANTY

NOTICE: To the extent consistent with applicable law, neither Manufacturer nor Seller makes any warranty, express or implied concerning the use, effects of, or results from use of this product, other than as indicated on this label. To the extent consistent with applicable law, buyer assumes all risks of use, storage and handling of this material not in strict accordance with directions contained on label.

Revised 05/20/09

[Following is sticker that will be placed on each culture plate (agar dish)]

GALLTROL-A EPA Reg. No. 40320-1

BIOLOGICAL PREVENTION OF CROWN GALL DISEASE

Active Ingredient: (*Agrobacterium radiobacter* St. K84: 99% w/w)

CAUTION: Keep out of Reach of Children

INSTRUCTIONS FOR USE:

1. Remove the lid & submerge agar plate in container of water, 1 gallon of water per plate.
2. While submerging plate in water, gently wipe off bacterial layer from agar surface with gloved hand. Do not break agar if to be used as a spray. Discard agar & dish.
3. If a slurry is made, agitate slurry suspension before adding to sprayer. Add water to a treatment volume of 1 gallon water per plate.
4. Treat plants ASAP (maximum 12 hours) after wounding. Discard unused suspension after 24 hours.

STORE IN REFRIGERATOR – DO NOT FREEZE

Do not use after 120 days of receipt.

READ FULL LABEL & INSTRUCTION FOR DETAILS

AgBioChem, Inc., 3 Fleetwood Ct., Orinda, CA 94563