



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 10, 2021

Matthew Brooks
Director, Ag-Chem Consulting LLC
Authorized Agent to AgBioChem, Inc.
12644 Chapel Road
Clifton, VA 20124

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Delete grape as a use site and update product label.
Product Name: Galltrol- A
EPA Registration Number: 40230-1
Application Date: 08/28/2020
Action Code Case Number: 00147996

Dear Mr. Brooks:

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 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

Page 2 of 2
EPA Reg. No. 40230-1
Action Code Case No. 00147996


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 Andrew Queen by phone at 703-308-8135 or via email at queen.andrew@epa.gov.

Sincerely,

**DANIEL
SCHOEFF**

 Digitally signed by DANIEL
SCHOEFF
Date: 2021.05.10 06:37:18
-04'00'

Daniel Schoeff, Acting Senior Regulator Advisor
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

May 7, 2021

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: <i>Agrobacterium radiobacter</i> (Strain 84)*.....	99.00%
OTHER INGREDIENTS:	1.00%
TOTAL:	100.00%

*1.2 x 10¹¹ c.f.u./plate (Equivalent to 1 liter of 1.2 x 10⁸ cells per ml.)
Each culture plate is 150 mm (6 inches) in diameter and 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

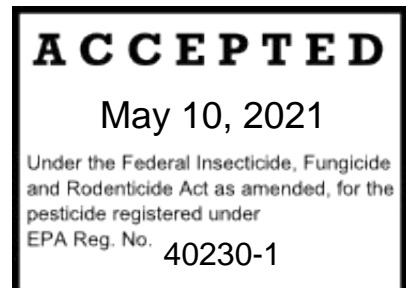
FIRST AID	
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
<ul style="list-style-type: none"> • Have the product container or label with you when calling a poison control center or doctor or going for treatment. • For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product, contact the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8AM to 12PM PST, or at http://npic.orst.edu. 	

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

Lot No.

Not for sale or use after [120 days
after the date of manufacture].

Manufactured in U.S.A. by
AgBioChem, Inc.
3750 North 1020 East
Provo UT 84604
(530) 586-1561
www.agbiochem.com



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 long pants
- Shoes plus socks
- Protective eyewear
- Waterproof gloves

Mixers/loaders and applicators must 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 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 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 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.

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), 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 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
- Waterproof gloves
- Shoes plus socks
- Protective eye wear

Use Precautions

- Keep GALLTROL-A refrigerated (35°- 40°F). Use as soon after receipt as possible. Do not use if frozen or allowed to get hot or dry.
- When preparing dip or spray suspensions of GALLTROL-A, use clean containers and non-chlorinated water free of copper, zinc or bactericidal materials to avoid loss of potency.
- GALLTROL-A bacteria may be inactivated by freezing or by exposure to high temperatures, sunlight and desiccation. Do not expose plates to sunlight. GALLTROL-A bacteria do not survive well from day to day in water. Mix fresh suspension of GALLTROL-A 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-A.

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, 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.)

May 7, 2021

GALLTROL-A is used at the rate of bacteria from 1 plate per gallon of water (non-chlorinated). 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 plate 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-A 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-A immediately prior to planting in seed bed.

Cutting Application: Dip or hand spray clean basal ends in GALLTROL-A 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-A suspension to cover roots and stem up to bud or graft union. One gallon of GALLTROL-A mix may treat following numbers of trees of specified caliper size: 200 trees @ $\frac{3}{4}$ "-1"; 300 trees @ $\frac{5}{8}$ "; 400 trees @ $\frac{1}{2}$ "; and 800 trees @ $\frac{1}{4}$ ". Amount of GALLTROL-A 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. Product expires 120 days after 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 must be disposed of on-site or at an approved waste disposal facility.

Container Disposal: Securely wrap petri plates and packaging in newspaper and dispose of these in a sanitary landfill. Do not burn.

WARRANTY

NOTICE: To the extent consistent with applicable law, neither Manufacturer nor Seller make 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 08/20/20

[The Following is a sticker that will be placed on the lid of each agar plate]

GALLTROL-A
BIOLOGICAL PREVENTION OF CROWN GALL DISEASE

ACTIVE INGREDIENT: <i>Agrobacterium radiobacter</i> (Strain 84)*	99.00%
OTHER INGREDIENTS:	1.00%
TOTAL:	100.00%

* 1.2×10^{11} c.f.u./plate (Equivalent to 1 liter of 1.2×10^8 cells per ml.)
See additional cautionary statements and directions for use inside pamphlet.

Keep out of Reach of Children
CAUTION/AVISO

DIRECTIONS FOR USE:

1. Remove the lid & submerge agar plate in container of non-chlorinated 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 & plate.
3. If a slurry is made, agitate slurry suspension before adding to sprayer. Add water to a treatment volume of 1gallon water per plate.
4. Treat plants ASAP (maximum 12 hours) after wounding. Discard unused suspension after 24 hours.

STORE IN REFRIGERATOR – DO NOT FREEZE

Not for sale or use after [120 days after the date of manufacture].

EPA Reg # 40320-1

EPA Est. # 40320-CA-001