

62388-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6/24/2014

1/13

JUN 24 2014

Mr. Gordon Sargent
Product Registration Manger
BASF Corporation
26 Davis Drive, P.O. Box 13528
Research Triangle Park, NC 27709

Re: BASF Corporation; NOGALL™
EPA Registration No. 62388-1
Minor Label ("Fast Track") Amendment
Submissions Dated 02/28/2014, 06/13/2014, and 06/16/2014
Decision No. 488313

Dear Mr Sargent:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

1. Addition of explanatory text in square brackets (i.e., comments to label reviewers).
2. Correction of minor formatting inconsistencies and typographical errors.
3. Modification of the referral statement for the Precautionary Statements and First Aid Box on the front panel of the label.
4. Removal of the reference to United States Patent 5,354,684 from the front and back panels of the label.
5. Modification of the registrant's name, the registrant's contact information (e.g., street address), and the Warranty Statements to reflect a recent company transfer.

CONCURRENCES

SYMBOL	▶ 7511P	7511P	7511P					
URNAME	▶ FORREST	Borgus	Uher					
DATE	▶ 6-17-14	6/24/14	6/24/14					

Gordon Sargent
EPA Registration No. 62388-1

- 6. Replacement of “Net Contents” with “Net Weight” as NOGALL™ is a solid (Chapter 17, Section III of the EPA’s Label Review Manual – Revised November 2012) and modification of the container sizes (in both U.S. and metric units) after “Net Weight.”
- 7. Modification of text related to the Expiration Date in accordance with 40 CFR § 156.10(g)(6).
- 8. Removal of the Keep Out Of Reach Of Children Statement, the Signal Word (one occurrence), the EPA Establishment Number, and the EPA Registration Number from the back panel of the label as these components already appear on the front panel of the label.
- 9. Addition of Hot Line Number information to the First Aid Box (Chapter 7, Section III(F) of the EPA’s Label Review Manual – Revised July 2012).
- 10. Modification of the following statement in the Hazards to Humans and Domestic Animals section (Chapter 7, Section III(D) of the EPA’s Label Review Manual – Revised July 2012) (changes emphasized):

“Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.”

- 11. Modification of the dust/mist filtering respirator text (to align with standard text found on the labels of other microbial pesticide products) in the Personal Protective Equipment section to the following:

“Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.”

- 12. Addition of Statements for Contaminated Personal Protective Equipment to the Personal Protective Equipment section (Chapter 10, Section VI(B) of the EPA’s Label Review Manual – Revised May 2014).
- 13. Modification of the User Safety Recommendations (Chapter 10, Section VI(D) of the EPA’s Label Review Manual – Revised May 2014).
- 14. Modification of certain text in the Environmental Hazards section (changes emphasized):

“Do not contaminate water when disposing of equipment washwaters or rinsate.”
(Chapter 8, Section III(A) of the EPA’s Label Review Manual – Revised September 2012).

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- 15. Modification of the following statement in the Directions for Use (changes emphasized):

“For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.”

(Chapter 10, Section VII(A) of the EPA’s Label Review Manual – Revised May 2014).

- 16. Adjustment of text in the Storage and Disposal Box to align with information presented in Chapter 13 of the EPA’s Label Review Manual (Revised July 2013) and to account for the intended packaging of the product (i.e., 3.5- and 17.6-ounce foil or plastic pouches in a box).
- 17. Addition of the following statements to the Directions for Use on the back panel of the label:

“See Safety Data Sheet for additional information.”

“For 24-hour emergency assistance, contact CHEMTREC at 1-800-424-9300 or BASF Corporation at 1-800-832-HELP (4357).”

- ~~18. Modification of the distributor’s contact information (e.g., street address).~~

- 19. Addition of statements regarding where the product is manufactured (i.e., “Product of Australia”) and the trademark status of NOGALL™ (i.e., “NOGALL™ is a Trademark of BASF”).

- 20. Addition of the Signal Word, the Keep Out Of Reach Of Children Statement, the Precautionary Statements, the EPA Registration Number, and the EPA Establishment Number to the label insert.

(Chapter 3, Section II(B) of the EPA’s Label Review Manual – Revised May 2012).

- 21. Modification and removal of several statements in the Directions for Use for clarification purposes (e.g., mixing instructions presented in U.S. and metric units).

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Mr. Robert A. Forrest by telephone (703-308-9376) or email (forrest.robert@epa.gov).

Gordon Sargent
EPA Registration No. 62388-1

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

Sincerely,



Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):

- NOGALL™ Stamped, Accepted Label
- A-79 Enclosure

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[Front Panel]

NOGALL™

For Biological Control of Crown Gall Disease

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

SEE BACK PANEL FOR FIRST AID & PRECAUTIONARY STATEMENTS

EPA Registration No.: 62388-1
EPA Establishment No.: 62388-AUS-001

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Manufactured by:
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

ACCEPTED

JUN 24 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 62388-1

Net Weight: 3.5 oz (100 g), 17.6 oz (500 g)

Not for sale or use after date stamped on side panel. [The date stamped on the side panel of this box is 6 months after the date of manufacture.]



The Chemical Company

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[Back Panel]

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

ACTIVE INGREDIENT:

Agrobacterium radiobacter (strain K1026).....0.03%*

OTHER INGREDIENTS:.....99.97%

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 x 10⁷ cfu per milliliter in the dip solution.

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.
HOT LINE 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 BASF Corporation for emergency medical treatment information at 1-800-832-HELP (4357).	

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 a long-sleeved shirt, long pants, waterproof gloves, shoes and socks. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. 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, 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 washwaters 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.

***Refer to Insert Label for Additional Directions for Use.**

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 personal protective equipment (PPE) and restricted-entry interval. 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 coveralls, shoes, socks and waterproof gloves.

CHEMIGATION

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

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 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 date of expiration 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.

See Safety Data Sheet for additional information.
For 24-hour emergency assistance, contact CHEMTREC at 1-800-424-9300
or BASF Corporation at 1-800-832-HELP (4357).

Manufactured by:
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

Distributed by:
New BioProducts Inc.
6421 NW Oak Creek Dr.
Corvallis, OR 97330 USA
Ph: (541) 752-2045, Fax: (541) 754-3968
Email: nbimike@comcast.net

Product of Australia

[Side Panel]

Batch No.:
Expiration Date:

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[Label Insert]

NOGALL™

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Registration No.: 62388-1
EPA Establishment No.: 62388-AUS-001

FIRST AID

If in eyes:

- 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.

HOT LINE 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 BASF Corporation for emergency medical treatment information at 1-800-832-HELP (4357).

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 a long-sleeved shirt, long pants, waterproof gloves, shoes and socks. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. 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, 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 washwaters 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.

USE INSTRUCTIONS & PRODUCT INFORMATION

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, 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 *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.

APPLICATION INSTRUCTIONS

Germinating Seed Application to almond, apricot, cherry, nectarine, peach, pecan, plum and walnut: Dip 15 pounds of seed into a suspension of NOGALL™

prepared by adding 3.5 oz (100 g) 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.

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 (3.5 oz (100 g) of NOGALL™ to 1 gallon 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 3.5 oz (100 g) of NOGALL™ to 1 gallon 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

NOGALL™ is shipped as packs of either 3.5 oz (100 g) or 17.6 oz (500 g) of concentrated, moist peat bacterial cultures. There are at least 1,000 million colony-forming units of *Agrobacterium radiobacter* strain K1026 per gram of product.

Stir vigorously and periodically stir solution during use. A 3.5 oz (100 g) or 17.6 oz (500 g) pack properly mixed in water will treat 1,000 and 5,000 bare root seedlings (1/4 inch caliper), respectively. DO NOT HOLD DILUTED SUSPENSION FOR MORE THAN 8 HOURS.

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 weather conditions, presence of other materials, or the

manner of use or application, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

BASF warrants that this product conforms to the chemical description on this 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, BASF 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 BASF'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT.

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

BASF 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 BASF.

Product of Australia

NOGALL™ is a Trademark of BASF

Manufactured by:



The Chemical Company
26 Davis Drive
Research Triangle Park, NC 27709

Distributed by:

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6421 NW Oak Creek Dr.
Corvallis, OR 97330, USA
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Email: nbimike@comcast.net